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Attorneys For Plaintiff MICHAEL ANGELO MORALES

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

MICHAEL ANGELO MORALES, Plaintiff, v. RODERICK Q. HICKMAN, Secretary of the California Department of Corrections; STEVEN ORNOSKI, Warden, San Quentin State Prison, San Quentin, CA; and DOES 1-50, Defendants.	Case No. C 06 219 (JF) **SECOND DECLARATION OF DR. MARK HEATH** **Date: January 26, 2006** **Time: 2 pm** **Courtroom: 3**

E.R. 0181

Dr. Mark Heath, under penalty of perjury, both deposes and states as follows:

1. I have reviewed the defendants' opposition to Mr. Morales's motion for a temporary restraining order, which was filed on Monday, January 23, 2006, as well as the exhibits submitted by the defendants. I have also reviewed press accounts of the executions of Clarence Ray Allen, Stanley "Tookie" Williams, and Donald Beardslee, as well as the execution logs of those executions. I would like to note for the record that this affidavit had been prepared in haste due to the limited time available and due to other work obligations that I am under.

2. I understand that the court has ordered the parties to discuss the use of pancuronium bromide and any problems that arose during CDC's three most recent executions. I discussed the Beardslee and Williams executions in my initial declaration, filed as Exhibit C to Plaintiff's Motion for a TRO. In this declaration, I discuss the Allen execution and the defendants' explanation of CDC's use of pancuronium bromide.

A. Recent Executions and the Need for a Second Dose of Potassium Chloride

3. Immediately following the execution of Clarence Ray Allen on Tuesday, January 17, 2006, defendant Steven Ornoski, Warden of San Quentin Prison, stated that the injection team was forced to administer a second dose of potassium chloride to Mr. Allen. *See* K. Fagan, *Reporter's Eyewitness Account of Allen's Execution*, SFGate.com, attached hereto as Exhibit 1. Warden Ornoski also stated that the injection team has used a second dose of potassium chloride in two previous executions.

4. The execution protocol used by the California Department of Corrections (CDC), known as Procedure No. 770, calls for a 100 mEq dose of potassium chloride to be administered as the last drug in the injection process. This dose of potassium, if rapidly administered to the inmate, is a lethal dose and should be sufficient to induce cardiac arrest. Procedure No. 770, moreover, makes no mention of the possibility that a second dose of potassium may be administered, the situations in which such a dose might be considered appropriate, the asserted medical necessity for a second dose, or whether the person making such an assessment has any medical training.

5. I have participated as an expert witness in two previous challenges to CDC's lethal injection procedure -- *Kevin Cooper v. Woodford*, No. C 04 436 JF, and *Beardslee v. Woodford*, No. C 04 5381 JF -- but the CDC has never before revealed that it has repeatedly been forced to employ a second dose of potassium chloride.

6. CDC's admission regarding the second dose of potassium chloride is disturbing. CDC asserts that after "the initial dose of potassium chloride was injected an agonal rhythm continued on the heart monitor." *See* Decl. of Jack St. Clair ¶ 7, Ex. 8 to Defendants' Opp. to Mot. for TRO. Notably, Dr. St. Clair's own log of this execution contains no mention of this agonal rhythm or the second administration of potassium chloride. It is impossible to determine with any degree of certainty why the CDC felt that the second dose was necessary in this situation, because CDC has not provided any information about its implementation of Procedure No. 770 or its conduct of individual executions, and Procedure No. 770, in the version currently available, does not provide any guidance whatsoever as to how the injection team should react to any contingency or problem that might arise during an execution.

7. The administration of the second dose of potassium chloride therefore raises a number of questions, including:

a) Why did the injection team feel that a second dose was necessary? The 100 mEq dose of potassium chloride should have been sufficient in itself to stop Mr. Allen's heart. The fact that the injection team deemed it insufficient may indicate problems with the administration of the drugs. Did the first dose of potassium not reach Mr. Allen because of a failure in the IV lines, injection site, syringe handling, or other error of administration, or did the first dose of potassium not reach Mr. Allen's heart because his circulation had collapsed?

b) If the failure of the first dose of potassium chloride to stop the heart was due to improper administration, did the same administration failure plague the injection of the sodium thiopental and pancuronium bromide? Was Mr. Allen properly

anesthetized and unconscious by the time the potassium was first administered? If so, what is the evidence for this?

c) How much potassium was administered in the second dose?

d) Given that Dr. St. Clair asserts that the second dose was necessitated by agonal rhythm on the EKG, why does Mr. Allen's execution log not contain any such notation of agonal rhythm or the administration of the second dose itself? Why does the execution log not provide a complete record of what happened? Are other execution logs incomplete as well?

e) Warden Ornoski explained the second dose to the press by stating, "this guy's heart has been beating for 76 years, and it took awhile for it to stop." This is not a satisfactory medical explanation for the need to administer a second dose of potassium chloride. A 100 mEq dose of potassium, when rapidly delivered into the circulation, should be sufficient to stop a person's heart regardless of how long that person has lived or how "strong" his or her heart might be. Warden Ornoski's explanation speaks to a minimal or absent background in medicine and underscores the inappropriateness of placing him in charge of the procedure. Given this lack of training, how does the Warden choose the injection personnel and devise the protocol? Does he consult with any experts with adequate qualifications? During the Allen execution, was anyone on the injection team sufficiently knowledgeable to be aware of how, medically speaking, the need for a second dose of potassium arose?

f) The fact that Procedure No. 770 does not even mention a second dose of potassium chloride, much less provide a procedure for determining when such a dose is necessary, indicates that the injection team simply reacts in an ad hoc fashion to situations as they occur and improvises a solution. Why does the CDC repeatedly allow such deviations from Procedure No. 770, while at the same time asserting that it is the CDC's sole source of execution procedures? Was the injection team following

any sort of procedure in giving the second dose? If so, why is that procedure not included in the protocol?

g) Who had the authority to order the second dose? What training or qualifications informed that person's decision?

h) By the CDC's own admission, two prior executions have also required a second dose of potassium chloride. Which two executions? What makes these executions different from the others in which a second dose is not required? Why is CDC achieving inconsistent results in its executions? Were these the same executions in which the CDC encountered difficulty in achieving intravenous access?

i) After the first execution in which a second dose was administered, did CDC consult with any experts -- particularly veterinarians with experience in euthanasia -- to address whatever problem occurred and develop a solution so that the need to give a second dose would not arise again? Did CDC consult with any other state corrections agencies that have more extensive experience in carrying out executions to determine whether the need for a second dose is a problem that can and should be corrected?

j) Once CDC was on notice that a situation could arise in which a second dose of potassium was necessary, why did it allow the same situation to arise in a second and, with Mr. Allen, a third execution? Have the three instances of additional dosing arisen from the same problem, or have three different problems led the CDC to administer a second dose on these occasions? If the former, why has CDC failed repeatedly to correct or anticipate the issue? If the latter, why is CDC's performance of the executions so erratic, and why does Procedure No. 770 not attempt to correct that?

k) Why did CDC not at least develop a procedure for administering a second dose, given that from prior experience it surely must have anticipated that the need for multiple potassium doses would likely arise again (as indeed it has)?

l) If the 100 mEq dose of potassium provided in Procedure No. 770 has proved inadequate in two previous executions, why has CDC not increased the dosage? Did CDC ever evaluate whether it should increase the dose of potassium? As stated above, 100 mEq should be a lethal dose, but the relatively high incidence of second doses may suggest that some factor unique to the execution process is rendering the dosage inadequate. If that is the case, the other drugs may be similarly affected as well. Has CDC evaluated whether, if the potassium dose is inadequate, the dose of thiopental might also be inadequate?

m) Regarding the first two executions requiring a second dose, do the execution logs reflect that a second potassium dose was given, and if so, why the injection team believed it necessary? If not, why do the logs not provide a complete record of what happened during the executions?

n) It should be noted that while the CDC does have a monitor in place for evaluating the efficacy of the potassium (the EKG), it has failed to deploy monitors for assessing the efficacy of the other drugs, thiopental and pancuronium. Monitoring devices that aid in assessing the efficacy of these drugs are widely used in clinical anesthesia practice. It is therefore difficult to understand why the CDC would apparently be more interested in monitoring the effectiveness of the potassium than the effectiveness of the thiopental or pancuronium. Is this discrepancy in the monitoring of the three drugs the result of a deliberate decision making process? If so, what factors influenced the decision, and who had authority to make the decision? What qualifications did that person have?

8. The CDC has not provided enough information to permit conclusive answers to these questions. It may be that there are reasons the CDC felt that it needed to administer two doses of potassium chloride to stop the heart that do not implicate failure of the drug delivery system and a risk of pain and suffering. But having the CDC produce enough information to answer these questions is vital to determining whether CDC is carrying out executions in a humane manner. The

Allen execution has demonstrated beyond doubt that CDC is willing to deviate from its protocol with little explanation, and the repeated problems highlight the inadequacy of CDC's planning for and conduct of executions.

B. The Use of Pancuronium Bromide

9. The primary reason that it is impossible to know whether the need to give Mr. Allen a second dose of potassium chloride was the result of conditions that rendered his execution inhumane, and more generally, whether individual executions carried out in California are accomplished in a humane manner, is CDC's use of pancuronium bromide to paralyze the inmate. Much of the risk of inhumane executions would be eliminated by having someone trained in assessing anesthetic depth evaluate the inmate after the sodium thiopental is administered, as is required by the American Veterinary Medical Association when potassium is used for euthanasia. The use of pancuronium bromide effectively prevents all witnesses to the execution from assessing whether the inmate is unconscious. Thus, the uncertainty surrounding the conduct of executions, and the difficulty of assessing the adequacy of the protocol, are traceable primarily to the use of pancuronium bromide.

10. Dr. Dershwitz has stated that pancuronium will mask the seizure-like body movements that may occur after an inmate's heart stops beating. Although a potassium chloride overdose administered to an unanesthetized person is known to cause severe pain and writhing body movements in response to that pain, it is not clear that the administration of potassium chloride to a properly anesthetized and unconscious human would cause such body movements. In the many legal cases in which I have participated, the defendants often have asserted that pancuronium will mask the manifestation of body movements caused by the potassium, but to my knowledge no state defendant has ever proffered any evidence as to the incidence of seizures, if any, upon potassium chloride after induction of anesthesia. At this point, it is somewhat speculative to say that such body movements will occur, much less what the nature and severity of those body movements would be.

11. If, as the defendants assert, the inmate is properly anesthetized, he would not be aware of any muscle contractions or body movements caused by the potassium and would not suffer as a result of them. The desire to prevent seizure-like body movements therefore must stem from a desire

to protect the sensibilities of witnesses and prison staff. I know of no medical, legal or ethical reason to subordinate the need to ensure a humane execution to the theoretical stress suffered by witnesses and staff, all of whom are present on a purely voluntary basis. Moreover, there are numerous other ways to protect witnesses and staff from potential psychological trauma: the inmate could be covered with a sheet; or CDC could explain the possibility of seizures to the witnesses and recommend that they avert their gaze if they are uncomfortable.

12. Significantly, the Ethics Committee of the American College of Critical Care Medicine has rejected concern for family members' sensibilities as a justification for the use of neuromuscular blockers when withdrawing ventilator support from critically ill patients. *See* R. Truog et al., *Recommendations for End-of-Life Care in the Intensive Care Unit*, 29 Crit. Care Med. 2332, 2345 (2001), attached hereto as Exhibit 2. The Committee made this determination in light of the substantial risk of suffering created by neuromuscular blockers: "NMBAs [neuromuscular blocking agents] possess no sedative or analgesic activity and can provide no comfort to the patient when they are administered at the time of withdrawal of life support. Clinicians cannot plausibly maintain that their intention in administering these agents in these circumstances is to benefit the patient. Indeed, unless the patient is also treated with adequate sedation and analgesia, the NMBAs may mask the signs of acute air hunger associated with ventilator withdrawal, leaving the patient to endure the agony of suffocation in silence and isolation. Although it is true that families may be distressed while observing a dying family member, the best way to relieve their suffering is by reassuring them of the patient's comfort through the use of adequate sedation and analgesia." *Id.* I agree, very strongly, with the views set forth by the Committee.

13. Finally, pancuronium bromide is not necessary to stop the inmate's breathing. As I stated in my previous declaration, the 5-gram dose of sodium thiopental on its own, if successfully delivered in entirety into the circulation, would eventually cause death by stopping the inmate's breathing. Before this can take place, however, the potassium chloride is administered to stop the inmate's heart. With respect to arresting respiratory function, therefore, pancuronium bromide serves no independent function within the execution protocol.

C. The Defendants' Mischaracterization of My Opinions

14. In its opposition brief, the defendants contend that I have altered the opinions that I asserted in previous lethal injection challenges. *See* Defendants' Opp. to Mot. for TRO, at 7. This is untrue.

15. My initial declaration was not intended as an exhaustive discussion of all of the flaws in Procedure No. 770 and the numerous ways in which it falls short of acceptable medical and veterinary practice. Rather, my declaration was meant as a summary of some of the ways in which Procedure No. 770 creates a significant risk of inhumane executions. If called to testify in this case, I would be prepared to discuss at length my opinions as to the flaws in CDC's protocol, which are based on my extensive research into lethal injection procedures and outcomes across the country.

16. Thus, I have not "abandoned" my opinion that, by failing to require a continuous infusion of sodium thiopental during the execution process, Procedure No. 770 creates the risk that the inmate will regain consciousness during the execution. *See* Ex. 4 to the Defendants' Opp., ¶ 23. I continue to believe that failure to provide a continuous thiopental infusion amplifies the risks engendered by the use of inadequately qualified personnel, the failure to assess and ensure anesthetic depth as required by the AVMA, the needless and unjustified use of pancuronium, and the needless and unjustified use of an ultra-short acting barbiturate.

17. The defendants conflate two different issues when they assert that my opinion as to the need for continuous infusion is incompatible with my opinion that 5 grams of sodium thiopental, administered at once, is a lethal dose. *See* Defendants' Opp. to Mot. for TRO, at 7. As discussed in my initial declaration, the sheer size of the dose of thiopental does not mitigate the risks inherent in having the drug administered remotely by untrained personnel. Even if the inmate is rendered unconscious at first, the short-acting nature of thiopental creates the risk that if only part of the dose reaches the inmate, he could regain consciousness during the execution. A continuous infusion is an additional safety measure that mitigates this danger, and is particularly important when the anesthetic is being administered by inadequately trained personnel. Notably, the initial design of the lethal injection protocol that was first introduced in Oklahoma called for a continuous infusion of sodium

thiopental, presumably on the assumption that this method of administration would help mitigate the risks created by inadequate training.

18. The defendants also assert that I have "abandon[ed]" my "reliance on autopsy reports." *See* Defendants' Opp. to Mot. for TRO, at 8. This is emphatically not the case. Toxicology data that is available from executions derives from piecemeal litigation across the country, which means that I now have a broader range of data regarding executions than at the time of the Beardslee execution. At that time, the limited set of toxicology data indicated that postmortem thiopental concentrations were often extremely low, and varied widely even between inmates executed under the same protocol. I believed then, and continue to believe, that this variation was cause for concern and should be explained. It was my opinion that the thiopental concentrations could be indicative of inconsistent administration of the lethal injection drug cocktail. *See* Ex. 5 to Defendants' Opp., ¶¶ 20-24. Since that time, I have had the opportunity to review toxicology reports from over 200 lethal injection procedures, as they have been made available as a result of discovery during litigation. My analysis of this much more extensive data set revealed that a phenomenon called "postmortem redistribution" causes a decline in measured thiopental concentrations when blood samples are obtained several hours after death. Based on this more recent analysis, it is now my opinion that toxicology reports based on blood drawn more than several hours after death do not contain data that can indicate whether or not an inmate was conscious during his execution. Just as such reports cannot prove that an inmate was conscious, they do not establish that he was unconscious.

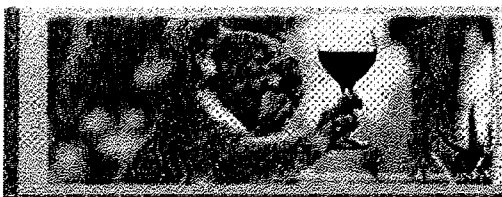
19. I and other experts continue to believe, however, that postmortem thiopental concentrations measured under certain conditions can provide evidence of an inmate's risk of consciousness during an execution. *See* M. Heath, D. Stanski, & D. Pounder, *Inadequate Anaesthesia in Lethal Injection for Execution*, 366 The Lancet 1073-74 (Sept. 2005) ("Post-mortem thiopental concentrations from blood drawn shortly after death can be quantitatively reliable and, in conjunction with autopsy and witness data, can provide evidence of a prisoner's potential risk of consciousness."), attached hereto as Exhibit 3.

20. The defendants' objections to purported changes in my opinions simply highlight the need for the CDC to fully disclose all information about the present and previous conduct of lethal injection procedures. As described above, it is only through the discovery process that an understanding of what is occurring during lethal injection can be achieved. The conduct of executions in California is cloaked in secrecy, particularly in comparison with many other States. Medical data becomes available only sporadically, as state corrections agencies are encouraged by courts to disclose information in litigation. Given that the medical features of lethal injection do not raise security or privacy considerations, it is difficult to understand why the CDC displays such a proclivity for secrecy.

I declare under penalty of perjury under the laws of the state of California and the United States of America that the foregoing is true and correct. Executed this 25th day of January, 2006 in New York City, New York.

By: 

Dr. Mark Heath



San Francisco Chronicle

Reporter's eyewitness account of Allen's execution

Kevin Fagan, Chronicle Staff Writer
Tuesday, January 17, 2006

The oldest man to ever enter California's execution chamber met his doom Tuesday the way he'd wanted to: With the faint lilt of Native American chants ringing in the air around him, and loved ones mouthing "I love you" to him as his damaged vision slowly faded to black.

A symbolic Indian feather lay on quadruple murderer Clarence Ray Allen's chest for the entire 33-minute execution, rising and falling until the lethal poisons piped into his veins through intravenous tubes stopped his breathing and he at last lay completely still.

"Hoka Hey, (an Indian saying meaning) it's a good day to die," Allen, who turned 76 on Monday, wrote in his last statement.

Those whose lives he savaged by ordering up the shotgun deaths of their loved ones in Fresno in 1980 looked as if they couldn't have agreed more.

Patricia Pendergrass, whose 27-year-old brother Bryon Schletewitz died when Allen's hitman blasted him

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Clarence Ray Allen

Ailing killer executed at age 76
(01/17/06)

Reporter's eyewitness account
(01/17/06)

A quieter protest outside San Quentin this time
(01/17/06)

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in the head, kept her hands clenched together and her lips pursed tightly from start to finish -- and then, as the official notice of his death was read off, she allowed herself the slightest hint of a smile. Five chairs to her right in the ring of witnesses sitting at a railing alongside the death chamber, prosecutor Ward Campbell lifted his chin as if in victory.

"Mr. Allen finally received the justice he deserved tonight," Campbell said a half-hour after the execution. "I was always confident this day would come. I am just very glad to have it finally be done."

It only took a few seconds after Allen walked into the heavily glassed, apple-green death chamber at precisely 12:05 a.m. to figure out this was not going to be the sort of execution many had predicted it would be.

Judges deny Allen's appeal -- reprieve sought
(01/16/06)

Inmate is first of many sick, aged in line at Death Row
(01/15/06)

Saunders: Ultimate justice delayed
(01/15/06)

Schwarzenegger denies clemency
(01/14/06)

Victims' families still grieve
(01/13/06)

Allen led a double life
(01/12/06)

Death Row's oldest inmate loses appeal
(01/11/06)

Vasquez: Why Allen's life should be spared
(01/06/06)

Allen, who has spent 23 years on Death Row, was said to be so ill from heart trouble and diabetes that he was blind, nearly deaf and could not walk. And indeed, when the oval door of the death chamber clanged open to begin the procedure, he was in a wheelchair.

But then he stood up.

The four guards alongside him -- two on each side -- put their hands under his shoulders and elbows to help him, but when his feet moved forward it was clear they did so on their own power. His portly face, pasty from living decades inside a cell, showed no pain as walked five steps to stand alongside the cross-shaped execution gurney.

He was a burly man, but when he put his thin arms on the sides of the gurney, he had little difficulty hoisting himself up and laying flat. And once he'd been strapped down and fit with the needles that would inject poisons into his tattooed arms, he vigorously craned his head and made eye contact with several people in the room.

He smiled broadly, calling out first, "Where are you?" and then, "I love you," as he raised his head several times to gaze at his former daughter-in-law, Kathy Allen, and four other supporters who came to watch him die. They smiled back, and when one of the women waved, he nodded his head.

It was all contrary to the impression given by his backers for months that he was an old man so feeble he would be unable to see anything, and would probably have to be carried bodily to the gurney. Such robust ability in someone whose eyesight was compromised by diabetes and who suffered a full heart attack just four months ago may have surprised some in the witness room --

but not prison officials who had been keeping close tabs on Allen.

"No shock to those of us who knew him," said San Quentin spokesman Vernell Crittendon, who also witnessed the execution, and all 12 others that have come before Allen since the state resumed executing inmates in 1992 . "I've watched him walk and read his own mail for a long time now."

Allen was referred to as a white man when he went to prison, but his Choctaw and Cherokee roots took on great important in the final years of his life -- and both his appearance Tuesday morning and the fact that he requested that his two spiritual advisors in the witness room be Native Americans testified to that.

He came into the death chamber with his long gray hair flowing to the middle of his back and held tight by a beaded headband of green, yellow and red. Around his neck was a white beaded necklace with an amulet hanging loosely down in front. He held a gray and white feather, with white leather thongs trailing off one end, in his manacled hands, and just before he was lashed tightly down by black straps he placed it on his chest.

The seven prison guards who spent from 12:05 to 12:17 strapping him to the gurney and inserting a needle in each arm -- the right needle digging in next to an eagle tattoo -- moved gingerly around the feather as they did their work. Unlike during the execution last month of Stanley Tookie Williams, the needle insertion went smoothly, taking just seven minutes instead of 13, with each needle sliding home easily.

Several guards patted Allen's shoulders and nudged his feather back in place as they worked. After taping his hands down to the gurney arms, mummy-style, they turned the gurney counter-clockwise a half-turn so he could see his supporters standing along the western wall of the witness chamber. Then they left and sealed the door. It was 12:17 a.m.

At 12:19, a piece of paper carrying the death warrant was shoved through a door porthole into the witness room, and a guard read it off. "The execution shall now proceed," she said.

In short order, unseen hands from behind the execution chamber walls sent three chemicals through the lines attached to the needles in Allen's arms: sodium pentothal to put him to sleep, pancuronium bromide to stop his breathing, and potassium chloride to stop his heart. A cardiac monitor attached to his chest registered him dead at 12:38 -- about five minutes longer than usual for the chemicals to work -- and Warden Steven Ornoski later said the staff had to send a second salvo of potassium chloride through the lines to finish the task.

"Basically, this guy's heart has been beating for 76 years, and it took awhile for it to stop," he explained. Two other executions required the same treatment.

While the strapping, inserting and injecting unfolded, the 50 witnesses watched mostly stoically, without speaking out loud. The silence was broken, eerily, by the distant sound of Indian chants

about halfway through the execution when 300 protesters at the eastern gate of the prison, several blocks away, sent their drumming and chanting through a loudspeaker system. Through the thick stone walls of the execution room, their strains could be slightly heard for several minutes.

Once the chanting stopped, the only audible noises were nervous coughs, muffled talking from behind the room walls, where the poisons were being dispatched, and the irritating "cheep, chip, cheep" whine of what sounded like a squeaky fan.

Along one wall, on a two-tier set of risers, stood Kathy Allen's group. One of them, legal researcher Denise Ferry, appeared to struggle with the strain of standing so long, squatting down several times and wiping her face. Another, a woman with long black hair and sunglasses, shook her head back and forth many times, holding her arms tightly to her chest. Kathy Allen looked griefstricken throughout the execution, and managed weak smiles only when Allen looked her way.

On the opposite wall were 17 media witnesses, and along the wall between the two groups were state officials and what appeared to be relatives of Allen's victims. Standing in front of that group were state Assemblywoman Sally Lieber, D-Mountain View, who co-wrote a bill calling for a moratorium on executions, and -- next to her -- Assemblyman Todd Spitzer, R-Orange, who opposes the bill.

Lieber spent most of the evening with her chin in her hand, staring intently into the chamber. Spitzer stared, too, but shortly after Allen's head stopped moving he began cracking his knuckles and looking at his watch, seeming eager for the procedure to end.

Seated at a railing in front of the window of the death chamber were seven relatives of the three people whose slayings sent him to Death Row: Schletewitz, Josephine Rocha, 17, and Douglas White, 20. The fourth person whose killing Allen ordered -- Mary Sue Kitts, 17 when she was strangled by a hitman in 1974 -- reportedly had no representatives there, because Allen's life prison term for her slaying pre-dated his capital sentence in the killing of the other three.

The murders were all related, though. Allen, who headed a theft ring in the 1970s, had ordered Kitts killed because she told Schletewitz that Allen led a burglary of the Schletewitz family store in Fresno, Fran's Market. Then while in Folsom prison for that murder, Allen sent a hitman after Schletewitz and seven others who testified against him -- and when the killer finally caught up with his first mark as he closed out his shift at Fran's Market one night in 1980, Rocha and White had the awful luck of also being on shift.

White's aunt and uncle sat in two chairs Tuesday. Rocha's sister sat in another. Jack Abbott, who ran to Fran's Market the night of the triple shooting and shot the hitman, wounding him, was at the railing too -- and locked eyes and waved grimly at Allen at one point.

Pendergrass, 55, and two young women -- one on either side, one reportedly her daughter -- sat in three other chairs. One of the young women twisted her hands together nervously, continuously, and when Allen's eyes closed for good and head stopped moving at

12:21 she bowed her head and seemed to pray.

"I don't think this execution will wipe away the pain," Pendergrass told The Chronicle last week. "But what it will do is close a chapter. He made not just our families victims, but those in his own family who must now lose him victims too -- we have all suffered, for different reasons. I want it to be done."

The emotion shone like fire from her eyes Tuesday morning as the certitude of Allen's death became clear.

Email Kevin Fagan at kfagan@sfchronicle.com.

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Recommendations for end-of-life care in the intensive care unit: The Ethics Committee of the Society of Critical Care Medicine

Robert D. Truog, MD; Alexandra F. M. Cist, MD; Sharon E. Brackett, RN, BSN; Jeffrey P. Burns, MD; Martha A. Q. Curley, RN, PhD, CCNS, FAAN; Marion Danis, MD; Michael A. DeVita, MD; Stanley H. Rosenbaum, MD; David M. Rothenberg, MD; Charles L. Sprung, MD; Sally A. Webb, MD; Ginger S. Wlody, RN, EdD, FCCM; William E. Hurford, MD

KEY WORDS: palliative care; intensive care; end-of-life care

These recommendations are intended to provide information and advice for clinicians who deliver end-of-life care in intensive care units (ICUs). The number of deaths that occur in the ICU after the withdrawal of life support is increasing, with one recent survey finding that 90% of patients who die in ICUs now do so after a decision to limit therapy (1). Although there is significant variability in the frequency of withdrawal of life support both within countries (2) and among cultures (3), the general trend is international in scope (4). Nevertheless, most evidence indicates that patients and families remain dissatisfied with the care they receive once a decision has been made to withdraw life support (5). Although intensive care clinicians traditionally have seen their goals as curing disease and restoring health and function, these goals must now expand when necessary to also include assuring patients of a "good death." Just as developments in knowledge and technology have dramatically enhanced our ability to restore patients to health, similar developments now make it possible for almost all patients to have a death that is dignified and free from pain.

The management of patients at the end of life can be divided into two phases. The first concerns the process of shared decision-making that leads from the pursuit of cure or recovery to the pursuit of comfort and freedom from pain. The second concerns the actions that are taken once this shift in goals has been made and focuses on both the humanistic and technical skills that must be enlisted to ensure that the needs of the patient and family are met. Although both of these issues are critically important in end-of-life care, the decision-making process is not unique to the ICU environment and has been addressed by others (6–11). These recommendations, therefore, do not deal primarily with the process that leads to the decision to forego life-prolonging treatments but rather focus on the implementation of that decision, with particular emphasis on the ICU environment.

This division of the process into two phases is necessarily somewhat artificial. Patients and families do not suddenly switch from the hope for survival and cure to the acceptance of death and pursuit of comfort. This process happens gradually over varying periods of time ranging from hours to weeks. Similarly, the forgoing of life-sustaining treatments rarely happens all at once and is likewise a stepwise process that parallels the shift in goals. Although acknowledging the relationship between the process of decision-making and the corresponding actions, these guidelines will focus on the latter.

These recommendations are written from the emerging perspective that palliative care and intensive care are not mutually exclusive options but rather should be coexistent (12–14). All intensive care patients are at an increased risk of mortality and can benefit from inclusion of the principles of palliative care in their management. The degree to which treatments are focused on cure vs. palliation depends on the clinical situation, but in principle both are always present to some degree. Figure 1 illustrates a useful paradigm for the integration of palliative care and curative care over the course of a patient's illness.

Although many patients are best served by transfer to other environments (e.g., home, hospice, or ward) that may be more conducive to palliative care, some patients are so dependent on ICU technology at the end of life that transfer is not possible. For those who are expected to survive for only a short time after the removal of life-sustaining technology, transfer of the patient to a new environment with new caregivers is awkward and may disrupt the patient's medical care. For these reasons, among others, intensive care clinicians must become as skilled and knowledgeable at forgoing life-sustaining treatments as they are at delivering care aimed at survival and cure.

Preparation of the Patient, the Family, and the Clinical Team

As the decision to forego further use of life-sustaining treatments is being made,

From the Ethics Committee, American College of Critical Care Medicine.

The American College of Critical Care Medicine (ACCM), which honors individuals for their achievements and contributions to multidisciplinary critical care medicine, is the consultative body of the Society of Critical Care Medicine (SCCM) that possesses recognized expertise in the practice of critical care. The ACCM has developed administrative guidelines and clinical practice parameters for the critical care practitioner. New guidelines and practice parameters are continually developed, and current ones are systematically reviewed and revised.

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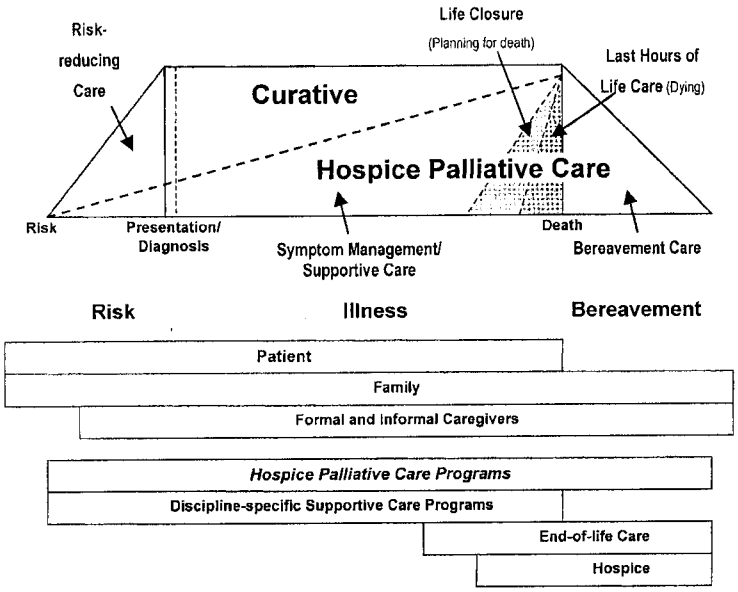

Figure 1. Palliative care within the experience of illness, bereavement, and risk. From Frank D. Ferris, MD, Medical Director, Palliative Care Standards/Outcomes, San Diego Hospice, 4311 Third Avenue, San Diego, CA, USA 92103–1407.

the family and clinical team must be prepared for what is to follow. As familiar as many clinicians may be with the process of withdrawing life support, it is a singular event in the life of the patient and often is unprecedented for family members. Therefore, they may suffer great anxiety during the experience. Clear and explicit explanations on the part of the clinician may alleviate anxiety and refocus familial expectations.

Needs of the Patient. The healthcare team has an obligation to provide care that relieves suffering arising from physical, emotional, social, and spiritual sources (7, 15–17). The patients in the study by Singer et al. (18) identified five domains of good end-of-life care: receiving adequate pain and symptom management, avoiding inappropriate prolongation of dying, achieving a sense of control, relieving burden, and strengthening relationships with loved ones.

Most patients have already lost consciousness by the time life-sustaining treatments are removed (4, 19). Some, however, such as those with cervical quadriplegia or amyotrophic lateral sclerosis, may be fully conscious. Whenever possible, patients should be prepared for the planned sequence of events and reassured about what they may experience.

Experience of hospice workers shows that the majority of dying patients fear pain and dyspnea (20). First and foremost, patients should be assured that management of their pain and distress will be the highest priority of their caregivers. Depending on personal preferences and spiritual considerations, some patients will want to be more sedated than others. Patients should understand, however, that the clinicians will take their cues from the patient and will try to tailor the administration of sedation and analgesia to the individual needs and desires of the patient.

Closely related is the need to assure patients that they will be treated with respect and dignity, both during and after the dying process. A policy that explicitly allows and encourages the continuous presence of family and friends at the bedside is one means of expressing this commitment. For patients who maintain relational capacity, the opportunity to say good-bye may be of paramount importance.

Patients should know that their cultural beliefs are understood and that cultural expectations will be met (13). Clinicians must plan ahead in this regard and be sure that they fully understand the relevant cultural expectations regarding the process of dying, the handling of the body after death, views about autopsy and organ donation, and cultural norms of grieving. Prior consultation with local representatives of cultural groups may be invaluable. Patients should be given every opportunity to experience spiritual meaning and fulfillment. Involvement of clergy will often be desirable, and performance of religious services and rites at the bedside should be encouraged (21). For children, cultural and spiritual observances should be oriented toward providing an age-appropriate understanding of dying, as well as providing the parents and family with meaningful rituals for coping with the death of a child.

Needs of the Family. Although the needs of the patient must be the primary focus of caregivers, there is growing consensus that a family-centered approach is particularly important in end-of-life care (22). Families of the dying need to be kept informed about what to expect and about what is happening during the dying process. Communication between clinicians and grieving families may be difficult in the absence of a prior relationship, as is frequently the case in the ICU. Primary care providers and other more familiar clinicians may be able to provide a helpful interface with the ICU team.

After conducting interviews, Hampe (23) identified eight needs of spouses of dying patients in the hospital setting: to be with the dying person; to be helpful; to be assured of the comfort of the dying person; to be informed of the person's condition; to be informed of impending death; to ventilate emotions; to be comforted and supported by family members; and to be accepted, supported, and comforted by health professionals. Parents of children in pediatric intensive care units have identified their own needs, which Meyer et al. (24) arranged in a useful hierarchy: physical needs such as hunger and sleep; safety of their child; ready access to their child; access to optimal health care, accurate information from the healthcare team; participation in their child's care; fulfillment of their parental role; social support; and emotional consolidation and acceptance. Family members may neglect their own physical and emotional needs, to the detriment of their ability to participate in decision-making and care.

The needs of families have been assessed by a survey tool known as the Critical Care Family Needs Inventory (25). A meta-analysis of several studies that have used this tool identified the most important family needs, many of which focused on the desire to have ongoing communication with the healthcare team (26). Combining information from a number of studies leads to a summary of the needs of families, as seen in Table 1 (23–25, 27, 28).

Table 1. Ten most important needs of families of critically ill dying patients

To be with the person
To be helpful to the dying person
To be informed of the dying person's changing condition
To understand what is being done to the patient and why
To be assured of the patient's comfort
To be comforted
To ventilate emotions
To be assured that their decisions were right
To find meaning in the dying of their loved one
To be fed, hydrated, and rested

Families need the opportunity to be with the dying person. Although not always possible, a private room is the environment most conducive to emotional and physical intimacy and should be identified as a goal for excellent care of the dying (as well as a legitimate factor in justifying this cost to third-party payers). Usual restrictions on visitation should be relaxed as much as possible, especially with regard to restrictions on children (in some hospitals, even pets have been allowed for short visits) (29). This also may mean accepting and tolerating large groups of family and friends at the bedside, which may be disconcerting to some clinicians. Whenever possible and within reason, withdrawal of life support should be timed to allow for the arrival of family members who must travel long distances. Not all families, however, want to be at the bedside at the time of the patient's death. Notifying the family that death is imminent should not be linked with an expectation that the family will be present. Families need to be reassured that it is also acceptable for them to remain at home.

Attention to detail can make an enormous difference. For example, providing the family with an electronic pager or cellular phone can allow them to break away for awhile without feeling out of contact. Clinicians can remind family members that they may want to contact clergy, friends, or others and can assist in making the calls if possible. Simple amenities like the presence of tissues, chairs, blankets, coffee, water, and a phone and general attention to the aesthetics of the room can contribute substantially to the family's sense of well-being and peacefulness. After the death of the patient, attention to detail may be greatly appreciated, as in freshly shaving the face of a man or clothing a child in her own pajamas (23).

Families vary in their tolerance for uncertainty and ambiguity, but clinicians, from the primary intensivist to the subspecialists to the nursing staff, should strive to deliver a consistent message. This may be facilitated by having all communication occur through the same person.

Families should clearly know the identity of the attending physician, understand that this person is ultimately responsible for the patient's care, and be assured of his or her involvement. Clinicians should avoid making firm predictions about the patient's clinical course, because these are notoriously difficult to make, are often inaccurate, and may result in a substantial loss of credibility when they are in error. Although clinicians should be sensitive and compassionate in their communication, it is important that they explain the physiologic process of dying and describe in concrete terms how the patient will die and what it will look like. At times it will be necessary for the clinicians to anticipate, ask, and answer questions that the family appears to be afraid or unable to verbalize. Families may benefit from reassurance that the clinicians are focused on the patient's comfort. Clinicians should earn the patient's and family's confidence by continually assessing the patient's suffering and demonstrating that pain-relieving medications and treatments are constantly available. Families should know that the caregivers are committed to having a presence at the bedside, even when the family members themselves are not able to be there. Finally, families often need to be reassured about the decisions they have already reached, emphasizing that the responsibility for these decisions is shared between the family and care team. This can help to dispel lingering doubts and potential feelings of guilt.

Families should have the opportunity to be helpful. They may be invited to participate in activities to relieve discomfort, such as mouth care, bathing, and repositioning. They should be encouraged to participate in assessment of the patient's pain and suffering. This is especially important in pediatrics and provides parents with an opportunity to express their nurturing role (16). Families also should be encouraged to bring in meaningful personal articles and be allowed to keep these articles at the patient's bedside.

Families should be encouraged to express their emotions. Both before and after the death of the patient, they should be given the opportunity to reflect on the patient's life and to recall shared memories. For neonates or young children, it may be necessary to create special memories through spiritual rituals or cultural tradition.

During the withdrawal of life support, all distractions should be eliminated so that the family's attention can be devoted entirely to the patient. In most cases, monitors should be turned off and the leads and cables should be removed from the patient. In some cases, catheters such as nasogastric tubes, urinary catheters, and arterial catheters also may be removed. In other situations, however, doing so may be more disruptive than beneficial. Even if there is the possibility that an autopsy may be required by the medical examiner, removal of catheters and tubes before death is not prohibited when this is done for the benefit of the patient and family (medical examiners may discourage or prohibit removal of lines and tubes after death, however). Bedrails can be lowered and restraints removed to allow family members more intimate contact with the patient. Although some family members may not desire to be at the bedside through the process of withdrawal, they should be given the opportunity to be present and possibly even to participate in the withdrawal of treatment. Finally, families should have private time to be with the patient after death and before removal of the body from the ICU.

Needs of the Clinical Team. Although all members of the clinical team should have active roles in providing end-of-life care, key aspects of this care should be performed and modeled by respected clinicians with leadership roles in the institution. These individuals are in a unique position to reinforce the message that excellent care at the end of life is an institutional priority. Attendings should affirm their leadership by personally supervising critical aspects of this care. For example, only 64% of Society of Critical Care Medicine (SCCM) physician members who perform extubation at the end of life remove the endotracheal tube themselves; the remainder presumably leave this task to nurses and respiratory therapists (30). Although removal of an endotracheal tube is clearly not a technically challenging procedure, personal involvement of the attending during this transitional event can send a powerful

message about the importance of end-of-life care.

The clinical team needs to be multidisciplinary and committed to cooperation and clear communication. A recent survey by Asch (31) pointed to difficulties in this area, with critical care nurses reportedly needing to engage in many covert practices that were in conflict with the physician's orders. These included administering more opioid than ordered and concealing the action by falsifying the amount "wasted," increasing doses of opioids when patients were already comatose, or only pretending to administer life-sustaining treatments that were ordered, such as by substituting saline for a vasopressor infusion (31). The methodology of this study has been harshly criticized, and many doubt that it represents an accurate picture of current critical care practices (32, 33). Nevertheless, it does suggest that nurses are concerned about the overuse of life-sustaining technology and the unresponsiveness of physicians to address this concern as well as the patients' pain and suffering. These concerns emphasize the need to develop a better consensus between physicians and nurses regarding the goals and strategies for providing end-of-life care in the ICU.

The Asch survey also pointed to the need for better education about end-of-life care and an institutional commitment to maintaining clinical competence. This is aided by providing clinicians with opportunities to gain knowledge concerning intensive palliative care. This education should focus on how to support and counsel families through the withdrawal process, ensure respect for various religious and cultural beliefs, and emphasize general communication and teamwork skills. Educational efforts need to be ongoing so that new staff are continually oriented to these competencies (13).

Clinical teams need administrative support. This begins by affirming the value of intensive palliative care at the highest levels of the institution and continues with protecting nursing staff from increased workloads when they are involved in delivering time-intensive palliative care. Administrators also can support intensive palliative care by allowing clinicians to minimize transfers of dying patients from the ICU to unfamiliar staff and locations, unless this is in the best interests of the patient and family.

Clinical teams need to have opportunities for bereavement and debriefing. One option is to have regularly scheduled meetings where staff can share their thoughts and experiences as well as critique the quality of the care they provided. This can be an opportunity to assess whether the patient experienced a "good death" and to discuss what went well and what could have gone better. These meetings also can be a forum for organizing a structured bereavement program that may include sympathy cards, follow-up phone calls, or distribution of educational materials to help guide families through the grieving process.

Ensuring the Comfort of the Patient

Intensive care medicine is so thoroughly grounded in the curative model of care that clinicians may have a difficult time "switching gears" and adopting a model focused primarily on symptomatology. An important difference between these models is the criteria used to determine whether a particular monitor, diagnostic test, or therapeutic intervention is indicated. In the curative model, the criteria are related to the degree to which the procedure will contribute to the patient's recovery from illness. In the palliative model, the criteria are related to whether the intervention will improve symptom relief, improve functional status, or ameliorate emotional, psychological, or spiritual concerns (13, 34). Only interventions that are favorable in this analysis should be used.

The transition from the curative to the palliative model often occurs in a piecemeal fashion. Sometimes the patient may receive an inconsistent combination of therapies, some aimed at comfort and some aimed at cure. One practical solution for dealing with this problem is to completely rewrite the patient's orders and care plan, just as if the patient were being newly admitted to the ICU. Each monitor, test, or intervention should be evaluated in terms of the degree to which it furthers the patient's goals before it is entered onto the order sheet. Some routine procedures that usually are considered an intrinsic part of ICU care, such as measuring vital signs, performing routine laboratory tests and chest radiograms, and endotracheal suctioning, may not contribute positively to the patient's comfort and should be excluded. On the other hand, some therapeutic procedures, such as the intravenous infusion of vasopressors or inotropes, may cause very little discomfort (requiring only the maintenance of intravenous access) but may substantially benefit the patient by maintaining perfusion of vital organs, thereby improving level of consciousness, renal and liver function, and gastrointestinal absorption. In some circumstances, such therapy might be reasonable, even in a terminally ill patient who is not receiving other life-prolonging therapies (35).

One caveat to this approach is that clinicians must interpret the goals of treatment from the perspective of the patient. For example, one study found that many cystic fibrosis patients were still taking vitamins on their last day of life, well after the point at which it was clear that they were very near death (36). Certainly the vitamins were not providing any "medical" benefit at this point, yet the authors surmised that the vitamins may have been part of a routine of care that the patient found comforting, and that altering this pattern or ritual of care as the patient approached death would have caused more distress than comfort. In this sense, then, some treatments may be indicated because of the psychological benefits (rather than strictly medical benefits) that they confer on the patient.

In most cases, however, rewriting the orders at the time that the goals of care are revised should reduce the use of monitors, tests, and procedures. Campbell and Frank (37) estimated that implementation of a comprehensive palliative care plan reduces the use of acute care interventions by approximately 50%.

Assessment of Pain. Many patients die with treatable pain, even in intensive care units (5). One probable reason for this is the strong bias in medicine toward the treatment of diseases rather than symptoms (e.g., the treatment for the acute abdominal pain of appendicitis is surgery, not morphine). Palliative care reverses these priorities and places symptom management ahead of diagnosis and definitive treatment. Another reason why pain is inadequately recognized and treated is because it is inherently subjective (e.g., "pain is whatever the patient says it is") and difficult to measure. Palliative care gives pain relief a high priority. The concept of pain as the "fifth vital sign" is one way of emphasizing the importance of treating pain assessment as a core element of patient care. The increased use of pain scales has provided for better quantification of the patient's experience. Un-

fortunately, pain scales may be better suited to postoperative and other forms of acute pain than they are to the chronic pain frequently experienced by dying patients.

Assessment of pain in dying patients often relies primarily on evaluation of level of consciousness and awareness, breathing pattern, and hemodynamics. Consciousness can be assessed by the patient's response to stimuli, by the patient's agitation or motor activity, and by facial expression. Bispectral analysis, which uses a processed electroencephalographic signal to assess a patient's level of consciousness, has been used as an adjunctive monitor for assessing patient comfort during the withdrawal of life support. Although this approach to pain assessment is at odds with the goal of reducing intrusive technology and monitoring at the end of life, in very rare circumstances it may have a role when assessment of distress is particularly difficult, such as in patients who are receiving neuromuscular blocking agents (see subsequent discussion) (19, 38).

Assessment of breathing patterns can be complicated in dying patients. Irregular breathing patterns are a natural part of dying and may not be uncomfortable for the patient. Unfortunately, the irregular pattern that accompanies dying is often referred to as "agonal," which may imply to the family and other clinicians that the patient is in "agony." Gasping is a medullary reflex and can occur in the absence of consciousness. Similarly, noisy respirations from airway secretions (the "death rattle") are more likely to be distressing to the family and other observers than they are to the patient. The question of whether clinicians should ever treat the patient primarily to relieve the distress of the family is considered subsequently.

The hemodynamic status of the patient (e.g., heart rate and blood pressure) is an unreliable indicator of pain, because tachycardia and hypertension can occur even in the absence of consciousness. Such hemodynamic signs may be more indicative of distress when they occur as part of a constellation of autonomic signs such as diaphoresis or lacrimation or when they occur in association with noxious stimuli.

The assessment of pain in neonates and small infants deserves special comment. Until recently, many clinicians believed that these patients had diminished capacity to experience pain and suffering and that they were more prone to serious side effects from the use of potent analgesic and anesthetic medications. Recent studies suggest, however, that pain pathways are functional from late gestation onward, and advances in anesthesiology and pediatrics have resulted in the development of safe anesthetic regimens and pain treatment protocols for patients of all ages (39–41). These insights extend the same emphasis on relief of pain and suffering that has become mandatory for adults to the clinical management of dying newborns and children (42).

Assessment of Suffering. "Pain" and "suffering" are not synonymous, but neither are they inherently distinct. In addition to its neurobiologic dimensions, pain also has powerful psychological and cultural components. Suffering is a more global term and includes consideration of the existential pain that is an essential part of the human condition. Some have argued that clinicians tend to be biased toward reductionistic interpretations of pain and suffering and often fail to attend to the broader and more difficult issues that may be of much greater importance to patients and families (43). The fact that there are not yet validated "suffering scales" does not diminish the importance of this dimension of the dying process.

Suffering may have profound meanings for patients that are unrelated to physical symptoms. Some patients, for example, may find redemptive meaning in their suffering and therefore may not want to avoid it entirely. By seeking to understand and appreciate these meanings, clinicians can individualize their care in ways that are responsive to these varying perspectives.

Nonpharmacologic Approaches to Pain and Suffering. "Dying in one's sleep" has always been viewed as a natural way to depart from this life. There are many physiologic reasons to support this view. Respiratory depression during dying may produce hypercarbia and hypoxia. Studies of alveolar anoxia suggest that the most rapid descent into unconsciousness with the least agitation occurs when hypoxia is allowed to progress in the face of normocarbia, a finding that could have relevance for approaches to ventilator withdrawal (see subsequent discussion) (44).

As cardiac activity decreases, hypoperfusion will decrease cerebral function. Decreased oral intake will lead to dehydration and a similar decrease in cerebral function. "Starvation euphoria" is a recognized phenomenon, possibly related to endogenous opioid production or the an-

Table 2. Possible physiologic consequences of forgoing specific therapies

System	Intervention	Effect of Withdrawal
Cardiovascular	Vasopressors	Vasodilation, hypotension (possible secondary tachycardia)
	Intra-aortic balloon pump	Decreased coronary perfusion, decreased cardiac output
	Left ventricular assist device	Decreased cardiac output
	Cardiac pacemaker	Asystole, bradycardia, decreased cardiac output
Pulmonary	Oxygen	Hypoxia, possible sympathetic discharge and increased respiratory drive, followed by respiratory depression
	Mechanical ventilation	Hypercapnia, increased respiratory drive (brainstem), depressed consciousness
	Positive end-expiratory pressure	Decreased functional residual capacity, ventilation-perfusion mismatching, hypoxia
	Extracorporeal membrane oxygenation and CO_2 removal	Hypoxia, hypercapnia, tachypnea, decreased cardiac output, tachycardia, bradycardia, asystole
	Nitric oxide	Pulmonary hypertension, hypoxia, decreased cardiac output
Renal	Dialysis	Acidosis, uremia, fluid overload, hyperkalemia, lethargy, delirium
Neurologic	Cerebrospinal fluid drainage	Increased intracranial pressure, leading to mechanical compression and hypoperfusion of cerebral structures
Nutritional	Nutrition and hydration	Lipolysis, ketosis, dehydration

algesic effects of ketosis (34). Table 2 summarizes the physiologic effects that accompany the foregoing of specific therapies and illustrates some of the ways that the withdrawal of treatments may actually contribute positively to the patient's comfort. Although these physiologic effects probably contribute to the comfort of dying patients, they are not uniformly effective. Some may make the patient more uncomfortable before the patient's consciousness diminishes. Accordingly, these physiologic effects should be attenuated by other measures.

Environmental factors can play an important role in promoting the patient's comfort. As noted previously, there are pros and cons to having dying patients remain in the ICU. The advantages include continuity of care and the greater availability of nurses and physicians. The benefits of leaving the ICU may include return to a more familiar (and possibly more private) setting, as well as less technology and cost. In either location, much can be done to enhance the patient's comfort, such as providing privacy and a comfortable bed, reducing lighting and noise, removing restraints, eliminating unnecessary monitors and machines, and providing the space and opportunity for interaction with the patient's family and loved ones (45–48). Beyond these simple measures, there may be cultural or spiritual factors, such as the opportunity for ritual, prayer, or music, that can increase the patient's comfort (49–51).

Opioids. Opioids have been a mainstay for the treatment of pain and suffering in dying patients (Table 3). Opiates are μ-receptor agonists, and central μ-receptors invoke analgesia, sedation, respiratory depression, constipation, urinary retention, nausea, and euphoria. Vasodilation may produce hypotension but also can have a therapeutic effect by decreasing venous return to the right heart, thereby decreasing filling pressures and relieving cardiogenic pulmonary edema. Practice parameters from the SCCM cite morphine as the preferred analgesic agent in the ICU, with hydromorphone and fentanyl as alternative agents (52).

Morphine is the most frequently used opioid analgesic in the United States, mainly because of its low cost, potency, analgesic efficacy, and euphoric effect. It has a half-life of 1.5–2 hrs in normal subjects after intravenous administration, but the elimination half-life may be prolonged in patients with hepatic or renal dysfunction. Although allergic reactions to morphine have been reported, it is much more common for allergic symptoms to be related to histamine release, especially when the medication is administered rapidly (52).

Fentanyl is a synthetic opiate with 80–100 times the potency of morphine. Fentanyl does not cause histamine release, which may explain the reduced incidence of hypotension compared with morphine. It has less sedative and euphoric effects compared with morphine. It has a half-life of 30–60 mins because of rapid redistribution, but with prolonged administration the elimination half-life increases to 9–16 hrs, as the peripheral sites of redistribution become saturated. Because both fentanyl and morphine reach 90% of their peak effect within 5 mins of intravenous administration, these medications can be safely redosed at 5-min intervals (53, 54). Hydromorphone is a semisynthetic morphine derivative, similar to morphine but with more potent analgesic and sedative properties and significantly less euphoria (52).

SCCM practice parameters recommend against the routine use of meperidine. Normeperidine is an active metabolite of meperidine that produces signs of central nervous system excitation such as apprehension, tremors, and/or seizures, especially in patients with renal insufficiency (52). The Agency for Health Care Policy and Research has recommended that meperidine should not be used except for a brief course of treatment in otherwise healthy patients who have demonstrated an unusual reaction or allergic response to morphine (meperidine does not cross-react in morphine allergy) (55, 56).

When intravenous access is either not possible or not desired, alternative routes of administration should be considered, including oral, rectal, subcutaneous, and transdermal. Long-acting formulations of several opioids are also available. Because most patients dying in intensive care units have intravenous access, and because these alternatives are extensively discussed in the palliative care literature, these other options for treatment are not reviewed here (57, 58).

Benzodiazepines. Benzodiazepines reduce anxiety and cause amnesia, important in preventing recall or breakthrough suffering. In addition to having a desirable synergistic sedative effect with opioids, benzodiazepines are anticonvul-

Table 3. Opioid analgesics

Medication	Equianalgesic Dosing, IV	Typical Starting Dose, Adult, IV	Typical Starting Dose, Pediatric, IV	Duration, hrs	Typical Starting Infusion Rate	Comments
Morphine	1	2–10 mg	0.1 mg/kg	3–4	0.05–0.1 $mg \cdot kg^{-1} \cdot hr^{-1}$	Histamine release (caution in asthma), vasodilation, hypotension
Hydromorphone	0.15	0.3–1.5 mg		3–4		Less pruritus, nausea, sedation, and euphoria than morphine
Fentanyl	0.01	50–100 μg	1–5 μg/kg	0.5–2.0	1–10 $\mu g \cdot kg^{-1} \cdot hr^{-1}$	Minimal hemodynamic effects, duration of action short when given by intermittent bolus, half-life prolonged when administered chronically
Meperidine	10	25–100 mg	1 mg/kg	2–4		Not recommended for chronic use; catastrophic interaction with MAO inhibitors; tachycardia; seizures

IV, intravenous; MAO, monoamine oxidase.
From Refs. 52, 55, 56, 59, 60, 67, 127.

sants and may help prevent the development of premorbid seizures.

Lorazepam is an intermediate-acting benzodiazepine that has a peak effect approximately 30 mins after intravenous administration. In adults, elimination is not altered by renal or hepatic dysfunction. The recommended starting dose is about 0.05 mg/kg every 2–4 hrs when administered by intermittent bolus (52).

Midazolam is a short-acting benzodiazepine. Because it is water soluble, it is not painful on peripheral injection. After intravenous administration, it undergoes a structural change to a lipophilic compound that rapidly penetrates the central nervous system and gives it an onset of action comparable to diazepam. It has a brief duration of action attributable to rapid redistribution, however, and administration by continuous infusion often is required for the medication to have a sustained effect. Starting doses for adults are 1 mg intravenously or 1–5 mg/hr by continuous infusion. Starting doses for children are 0.1 mg/kg intravenously or 0.05–0.10 $mg \cdot kg^{-1} \cdot hr^{-1}$ (52, 59–61).

Neuroleptics. Neuroleptics may be effective when the patient is manifesting signs and symptoms of delirium. Delirium is an acute confusional state that can be difficult to differentiate from anxiety, yet the distinction is important, because the administration of opioids or benzodiazepines as initial treatment for delirium can worsen the symptoms (52). Haloperidol has proven efficacy in the management of delirium. Although the drug does not possess a significant sedative effect, patients whose delirium is ameliorated by haloperidol often require less sedation with other agents (52). In addition, in one study this agent was used at least occasionally as an adjunct to the discontinuation of life-sustaining measures by 24% of physicians (30).

Starting doses of haloperidol in adults range from 0.5 to 20 mg, depending on the severity of the patient's delirium. Additional doses should be titrated at 30-min intervals until the patient's symptoms are controlled (62). Doses up to 50 or 60 mg may be required. Once delirium is controlled, patients often can be maintained on 50% to 100% of this amount in divided doses over 24 hrs (52). Haloperidol also has been administered successfully by continuous infusion, at doses ranging from 3 to 25 mg/hr (63).

Disadvantages of haloperidol include extrapyramidal symptoms, which are less common when the drug is given intravenously as opposed to enterally. Extrapyramidal symptoms are more common in children, reducing the usefulness of this medication in the pediatric population (64).

Propofol. Propofol is a sedative and anesthetic agent that is attractive primarily because of its short half-life. In most studies of ICU sedation, it has had a comparable effect to a continuous infusion of midazolam (52, 65). Low doses can be titrated to achieve varying planes of sedation or unconsciousness. A typical starting dose of propofol for both adults and children is 1 mg/kg, but some patients may become hypotensive with even this much, emphasizing the need to titrate to effect. When administered by infusion, a typical starting dose is 0.5 $mg \cdot kg^{-1} \cdot hr^{-1}$, with most patients requiring between 0.5 and 3.0 $mg \cdot kg^{-1} \cdot hr^{-1}$. The potential for drug incompatibility is a problem with propofol, because it requires that propofol be administered through a dedicated intravenous catheter. In addition, because of the potential for contamination and infection, the manufacturer recommends that propofol infusion bottles and tubing be changed every 12 hrs and that solutions transferred from the original container be discarded every 6 hrs. Like diazepam, propofol is painful when administered via a peripheral vein (52).

Barbiturates. Barbiturates have both advantages and disadvantages when used at the end of life. Their disadvantages include an absence of analgesic effect, necessitating the concurrent administration of analgesics (e.g., opioids) whenever the patient's symptoms include pain. Barbiturates also have been strongly linked to the practice of euthanasia, having been used for that purpose in the Netherlands and for the execution of prisoners by lethal injection in the United States. Even when appropriately administered within existing guidelines, therefore, their use could be misinterpreted as the practice of euthanasia. Advantages of barbiturates include their ability to reliably and rapidly cause unconsciousness, which may be necessary for the rare patient whose pain does not respond to any other approach (66). In addition, because their mechanism of action differs from the opioids and benzodiazepines, they may be useful in patients who have developed extreme levels of tolerance to these other medications. On balance, although barbiturates are very helpful in limited circumstances, they are not in the first line of medications that should be used in treating the terminally ill. Propofol offers many of the same advantages as the barbiturates without the complicating features. A typical starting dose for pentobarbital, a barbiturate with a medium duration of action, is 150 mg intravenously for adults and 2–6 mg/kg intravenously for children. For prolonged effect, the medication may be continued in doses of 3–5 $mg \cdot kg^{-1} \cdot hr^{-1}$. Because tolerance develops rapidly, progressive escalation of the dose is often necessary (66, 67). These adjunctive agents are summarized in Table 4.

Principles for Dosing and Titration. Although starting doses for sedation and analgesia were discussed previously and included in the tables, in many cases these doses will be irrelevant, because most patients will have already received these agents and will have already developed some tolerance to their effects at the time of withdrawal of life support. These agents should be titrated to effect, and the dose should not be limited solely on the basis of "recommended" or "suggested" maximal doses. In most cases, patients who do not respond to a given dose of an opioid or benzodiazepine will respond if the dose is increased—there is no theoretical or practical maximal dose. In rare cases, this generalization does not hold; in these patients, alternative classes of agents (like barbiturates or propofol) should be considered.

Current ethical and legal guidelines place importance on the intentions of clinicians in administering analgesics and sedatives at the end of life. Specifically, clinicians should administer doses that are intended to relieve pain and suffering but not intended to directly cause death. Because intentions are essentially subjective and private, the only ways to infer the nature of an individual's intentions are by self-report and by an analysis of his or her actions. Accordingly, documentation of one's intentions in the patient's chart is an important part of providing end-of-life care. When "p.r.n." orders are written for analgesics and sedatives, the indication for administration should be stated clearly (e.g., pain, anxiety, shortness of breath). This reduces the likelihood of misinterpretation or abuse. With regard to actions, when a clinician titrates morphine in doses of 1, 5, or 10 mg every 10 or 20 mins, it is plausible to conclude that the clinician intends to make the patient comfortable and not to directly cause the patient's death. On the other

Table 4. Adjunctive agents

Medication	Typical Starting Dose, Adult, IV	Typical Starting Dose, Pediatric, IV	Duration, hrs	Typical Starting Infusion Rate, Adult	Typical Starting Infusion Rate, Pediatric	Comments
Lorazepam	1–3 mg	0.05 mg/kg	2–4	0.025–0.05 $mg \cdot kg^{-1} \cdot hr^{-1}$	0.05–0.1 $mg \cdot kg^{-1} \cdot hr^{-1}$	Longer acting, ideal for long-term administration
Midazolam	1 mg	0.1 mg/kg	1.5–2	1–5 mg/hr	0.05–0.1 $mg \cdot kg^{-1} \cdot hr^{-1}$	Well tolerated but fairly expensive
Haloperidol	0.5–20 mg		2–4	3–5 mg/hr IV		Not often used in pediatrics because extrapyramidal effects more frequent
Propofol	1 mg/kg	1 mg/kg	10–15min	0.5–3.0 $mg \cdot kg^{-1} \cdot hr^{-1}$	0.5–3.0 $mg \cdot kg^{-1} \cdot hr^{-1}$	Hypotension, lipid base lead to hyperlipidemia, painful on injection
Pentobarbital	150 mg	2–6 mg/kg	2–4	3–5 $mg \cdot kg^{-1} \cdot hr^{-1}$	3–5 $mg \cdot kg^{-1} \cdot hr^{-1}$	Propofol should replace pentobarbital in most end-of-life situations

IV, intravenous.
From Refs. 52, 59–65, 71.

hand, when a clinician administers 2 g of morphine acutely to a patient who is not profoundly tolerant, it is difficult not to conclude that the clinician did intend the death of the patient.

The concept of "anticipatory dosing" (as opposed to reactive dosing) also should guide clinicians in the use of sedation and analgesia at the end of life. The rapid withdrawal of mechanical ventilation is an example of the need for anticipatory dosing. At the time of ventilator withdrawal, the clinician can anticipate that there will be a sudden increase in dyspnea. It is not sufficient simply to respond to this distress with titrated doses of an opioid (reactive dosing). Rather, clinicians should anticipate this sudden event and provide adequate medication beforehand (anticipatory dosing). As a general rule, the doses of medication that the patient has been receiving hourly should be increased by two- or three-fold and administered acutely before withdrawing mechanical ventilation.

There are some data on the use of sedatives and opioids during the withdrawal of life support. In one study, noncomatose adult patients received analgesia and sedation during withdrawal of life support, with an increase in benzodiazepine from a dose equivalent to 2.2 mg/hr of diazepam to 9.8 mg/hr and an increase in opioid from a dose equivalent to 3.3 mg/hr of morphine to 11.2 mg/hr at the time that life support was withdrawn (68). A retrospective study of three adult ICUs found that large doses of morphine (mean, 21 ± 33 mg/hr) and benzodiazepines (equivalent to a mean diazepam dose of 8.6 ± 11 mg/hr) were given during the withdrawal of life support (69). A similar study performed in pediatric ICUs found an increase in diazepam equivalents from 0.26 to 0.68 $mg \cdot kg^{-1} \cdot hr^{-1}$ and an increase in morphine equivalents from 0.54 to 1.80 $mg \cdot kg^{-1} \cdot hr^{-1}$ during the withdrawal of ventilator support (70). In addition, a review of 121 neonatal deaths reported that most patients (84%) received analgesia as their life support was withdrawn, and that most of these patients (64%) could be managed with doses of morphine in the usual pharmacologic range (0.1–0.2 mg/kg intravenously). Infants who were tolerant to morphine required larger doses, up to 1 mg/kg intravenously. Of particular note, there was no relationship between the dose of morphine used and the time until death after ventilator withdrawal (42).

Alleviation of Specific Symptoms. Campbell (29) called attention to many of the specific symptoms that may be experienced by terminally ill patients. Dyspnea is a form of suffering and is probably the most important symptom that must be relieved for patients dying in the ICU. The incidence of this problem is not well described, but data suggest that it is present in up to half of dying persons (29). Although dyspnea in patients dying of respiratory failure is almost always attributable to progression of their underlying disease, clinicians should remember that the differential diagnosis for dyspnea is extensive and includes many potentially treatable conditions such as reactive airway disease, infection, pneumothorax, congestive heart failure, and anxiety. The response to this sensation is both physiologic (e.g., tachycardia, tachypnea) and psychological (e.g., panic, anxiety, fear). Assessment should include an investigation for potentially treatable causes before focusing on symptom management. Symptom severity scales, such as the modified Borg dyspnea scale and the Bizek agitation scale, can be used to assess symptoms associated with breathlessness (29, 71–73).

Treatment of dyspnea may include pharmacologic and nonpharmacologic strategies. Simple positioning may be effective. Patients with chronic obstructive pulmonary disease may be most comfortable sitting up or leaning over a bedside table. Patients with unilateral lung disease (e.g., pneumonia) may prefer lying on one side more than the other.

Pharmacologic approaches to dyspnea are varied. Oxygen may enhance patient comfort by relieving hypoxemia (74). However, one study of advanced cancer patients reported that oxygen was no better than air in relieving dyspnea (75). Sometimes patients experience symptomatic relief by having air from a fan blowing gently on their face and may have increased dyspnea from a feeling of claustrophobia associated with the administration of oxygen by a facemask. Opioids relieve dyspnea by depressing respiratory drive, producing sedation and euphoria, and causing vasodilation, which can reduce pulmonary vascular congestion. Patients also may benefit from the judicious use of bronchodilators and diuretics to relieve small airway obstruction and pulmonary vascular congestion.

Nausea and vomiting are frequently reported at the end of life. As with dys-

pnea, potentially treatable causes should be investigated before resorting to symptomatic management. Most nausea and vomiting can be controlled with antiemetic agents. Although nasogastric drainage is sometimes effective for relief from profound ileus or small bowel obstruction, it may be more uncomfortable for the patient than occasional emesis.

Hunger and thirst are problematic concerns at the end of life. Some believe that the dying should always be given food and fluids and that this is a basic expression of our humanity and capacity for compassion (see "minority opinion" in Ref. 11). On this view, some caregivers believe that hunger and thirst should always be treated and encourage placement of nasogastric or gastrostomy tubes in terminally ill patients to administer nutrition when patients are no longer capable of oral sustenance. Current palliative care practices, however, recognize that loss of hunger and thirst are normal physiologic responses to the dying process, and that forced nutrition and hydration in this setting not only prolong the dying process but do not contribute to the patient's comfort (76–78). In addition, the metabolic abnormalities associated with dehydration tend to contribute to sedation and diminished consciousness rather than cause distress (76, 79). Although the symbolism associated with providing food and fluid should not be dismissed lightly, the majority view in the United States now holds that food and fluid should be provided if they are desired by the patient and contribute to the patient's comfort; otherwise, they may be foregone (78, 80).

Skin ulceration may be caused by local tissue conditions, infection, or ischemia from hypoperfusion and localized pressure or edema. Even the best skin care regimens are unlikely to promote healing under these conditions. The frequent turning and dressing changes that are required can cause more pain and discomfort than benefit. Attention to keeping the patient clean, dry, and free from odor may be the best goal under some circumstances.

Fevers and infections frequently occur in critically ill and dying patients. Because fever can be quite uncomfortable, antipyretics generally should be used. External cooling with ice packs, cooling blankets, or alcohol baths may create greater distress for the patient than the fever itself. Antibiotics may offer more benefit than burden for painful infections, such as otitis media, oral candidiasis, or herpetic infections.

Anxiety and delirium often occur at the end of life. The use of physical restraints should be avoided whenever possible. Pharmacologic management should be gauged more toward the patient's comfort and peacefulness rather than toward resolution of the delirium.

Withdrawal of Life-Sustaining Treatments

The indications for any proposed intervention in a dying patient should be assessed in terms of the goals of the patient. Any intervention that does not advance the patient's goals should be eliminated. This simple advice is persuasive in concept yet difficult to follow. In reality, physicians have many biases and preferences regarding the withdrawal of life-sustaining therapies that do not seem to be related to the needs or values of the patient. For example, a 1992 survey of SCCM physicians found that 15% almost never withdraw mechanical ventilation and that internists and pediatricians were more likely to withdraw mechanical ventilation than surgeons or anesthesiologists (30). Unless these differences were attributable to underlying systematic differences in the patient populations they cared for, the origins of these variations in practice must rest primarily with the preferences of the physicians themselves (81).

Some of these preferences are related to culture and religious beliefs. Some Jewish clinicians, for example, have religious reasons for believing that the withdrawal of life-sustaining treatments is "killing" and therefore is prohibited (4). In addition to these differences based on culture or religion, Christakis and Asch (82) reported that physicians prefer to withdraw therapy supporting organs that failed for natural vs. iatrogenic reasons, to withdraw recently instituted vs. long-standing interventions, to withdraw therapies leading to immediate death rather than delayed death, but to withdraw therapies leading to delayed death when faced with diagnostic uncertainty (82). There were also patterns in the preferences of physicians for the order in which treatments were withdrawn: first being blood products, followed by hemodialysis, vasopressors, mechanical ventilation, total parenteral nutrition, antibiotics, intravenous fluids, and finally tube feedings. There was an underlying trend toward earlier withdrawal of treatments perceived as more artificial, scarce, or expensive (82–84). Specialists have also been reported to prefer to withdraw the therapy with which they are most familiar; for example, pulmonologists withdraw mechanical ventilation, nephrologists withdraw dialysis, and so forth (85). Decisions in pediatrics are also stereotyped, with deaths in most series almost always following the withholding or withdrawal of either mechanical ventilation or extracorporeal membrane oxygenation (86, 87).

In light of these (perhaps unconscious) biases, it is useful to review the wide range of life-sustaining treatments that are used in critical care medicine and to work toward an approach that is less centered on physician preferences and more focused on the unique situation and needs of the patient. Table 5 catalogs the types of life-sustaining treatments that may be withdrawn and illustrates the range of therapies that may be foregone, from measuring and recording vital signs to extracorporeal membrane oxygenation.

Terminal Extubation vs. Terminal Wean

Grenvik (88) was the first to describe a systematic approach to ventilator withdrawal at the end of life and advocated a gradual reduction in the ventilator settings over several hours. Since then, there has been an ongoing debate regarding the best method of withdrawing mechanical ventilation. Although the early literature recommended blood gas monitoring during the withdrawal of ventilation, virtually all now agree that neither this nor noninvasive forms of respiratory monitoring are consistent with the palliative goals of promoting the patient's comfort and reducing technology whenever possible.

One recommended approach, commonly referred to as "terminal extubation," involves removal of the endotracheal tube, usually after the administration of boluses of sedatives and/or analgesics. The second technique, known as a "terminal wean," is performed by gradually reducing the F_{IO_2} and/or the mandatory ventilator rate, leading to the progressive development of hypoxemia and hypercarbia. In the latter technique there is considerably variability in the pace of the process, with some completing the wean over several minutes (19,

Table 5. Treatments that can be withheld or withdrawn

Therapeutic Goal	Therapy
Circulatory homeostasis	Cardiopulmonary resuscitation
	Vasopressors and inotropic medication
	Antihypertensive medication
	External ventricular assist/replacement device
	Implantable ventricular assist/replacement device
	Pacemaker
	Implantable cardiac defibrillator
	Intra-aortic balloon counterpulsation
	Transfusion of blood products, albumin
	Intravenous crystalloid administration
	Invasive pressure monitoring
Respiratory homeostasis	Mechanical ventilation
	Supplemental oxygen
	Artificial airway (endotracheal tube, tracheostomy tube, oral-pharyngeal airway)
	Extra-corporeal membrane oxygenation or CO_2 elimination
	Diaphragmatic pacing
Renal homeostasis	Hemodialysis (continuous or intermittent)
	Hemofiltration
	Peritoneal dialysis
Neurologic homeostasis	Cerebrospinal fluid drainage (may be palliative)
	Intracranial pressure monitoring
	Steroids, mannitol, hyperventilation
	Anticonvulsants (probably would continue for palliative reasons)
Endocrinologic homeostasis	Steroids (may be palliative)
	Hormone supplementation or suppression (may be palliative)
Treatment of infection, inflammation, or neoplasm	Antibiotic, antifungal, antiparasitic, antiviral medications (may be palliative)
	Anti-inflammatory medications (may be palliative)
	Immune "booster" medications
	Cytotoxic medication (may be palliative)
	Radiation therapy (may be palliative)
Nutritional homeostasis	Total parenteral nutrition
	Enteral feeding via gastric or jejunal tube
	Intravenous dextrose
"Routine" measures	Frequent phlebotomy for laboratory tests
	Frequent vital sign measurements
	Radiologic examinations
	Aggressive chest physiotherapy and endotracheal suctioning
	Placement of intravenous and intra-arterial lines
	Debridement of wounds

89–91) and others stretching it over several days (92).

The preferred approach varies widely. A 1992 survey of SCCM physicians found that 33% preferred terminal weaning, 13% preferred extubation, and the remainder used both. These preferences were correlated with specialty: Surgeons and anesthesiologists were more likely to use terminal weaning, whereas internists and pediatricians were more likely to use extubation ($p < .0001$) (30).

The principle advantage of the terminal wean is that patients do not develop any signs of upper airway obstruction during the withdrawal of ventilation. They therefore do not develop distress from either stridor or oral secretions, and if the wean is performed slowly with the administration of sedatives and analgesics, they do not develop symptoms of acute air hunger. These advantages not only promote the comfort of the patient but reduce the anxiety of family and caregivers (93).

Another cited advantage of terminal weans is that they are perceived to diminish the moral burden of the family and caregivers, presumably because the terminal wean is perceived as being less "active" than terminal extubation (30). Whether this is an advantage or disadvantage remains controversial. There is a risk that terminal weans may be perceived by families as *bona fide* attempts to have the patient successfully survive separation from the ventilator, even when this is not the expectation or intent of the clinicians—particularly when the wean is prolonged over several days. Terminal weans therefore should not be adopted as a means of avoiding difficult conversations with families about the patient's condition and prognosis.

In contrast to terminal weans, terminal extubations have the principal advantages that they do not prolong the dying process and that they allow the patient to be free from an "unnatural" endotracheal tube (94). The process of terminal extubation also is morally transparent; the intentions of the clinicians are clear, and the process cannot be confused with a therapeutic wean (30).

Although these two concepts have become fairly well entrenched into the lexicon of critical care medicine, we believe that the terminology of terminal weans and terminal extubations is confusing and should be replaced by more specific descriptions of the process. The use of the word *terminal* suggests that withdrawal will directly result in death of the patient. Occasionally, however, patients who are separated from the ventilator with the expectation of failure survive to be discharged from the intensive care unit or the hospital (95). *Weaning* generally refers to a therapeutic procedure that occurs when patients are improving and expected to survive. It may be unclear whether the process includes removal of the artificial airway, supplemental oxygen, or positive pressure ventilation. We believe it is preferable to use specific terms and to consider each of these therapies separately. An artificial airway may be removed (extubation), the patient may have supplemental oxygen discontinued, and/or positive pressure ventilation may be reduced or eliminated. These approaches are not mutually exclusive. For example, withdrawal of the artificial airway may occur simultaneously with the withdrawal of oxygenation and ventilation (terminal extubation). Ventilation and oxygenation also may be withdrawn rapidly (by transitioning to a T-piece) or slowly (by gradually reducing the F_{IO_2} and/or ventilator rate). Then, as the patient's pharmacologic sedation is supplemented by the effects of hypoventilation and hypoxia, the artificial airway may be withdrawn. It is conceivable that each therapy (artificial airway, supplemental oxygenation, and mechanical ventilation) may be continued or eliminated, depending on the specific circumstances of the patient. In this way, decisions can be made more specifically and deliberately

than when the choices are only between terminal wean and terminal extubation.

Finally, the method of withdrawal has important implications for the administration of sedation and analgesia. Abrupt changes in the patient's level of distress require the administration of anticipatory doses of analgesics and sedatives. If the decision is made to rapidly withdraw the artificial airway (extubation) or mechanical ventilation (transition to T-piece), for example, the patient generally should receive medication before the withdrawal in anticipation of distress, with subsequent doses titrated to the patient's level of comfort.

Withdrawal Prototypes

No two instances of the withdrawal of life support are ever identical, yet certain prototypes have a number of features in common. They depend on the clinical characteristics of the patient and the type of life support that is being withdrawn. These were discussed in more detail by Campbell (29).

Ventilator Withdrawal from Patients Declared Brain Dead. Patients who have been declared brain dead are dead. Removal of the ventilator is not the withdrawal of life support, because the ventilator is not supporting life. The most straightforward approach to withdrawal of the ventilator in these circumstances is rapid removal of the artificial airway, oxygenation, and ventilation.

Clinicians should be aware, however, that brain dead patients may rarely exhibit dramatic movements, caused by the firing of spinal motor neurons, that are known as the Lazarus sign (96, 97). Such movements generally occur either during the apnea test or after the withdrawal of mechanical ventilation and are thought to be related to acute effects of hypoxia or ischemia on spinal motor neurons. The movements can be as extensive and complex as the patient sitting up in bed. Because current brain death criteria do not require the loss of all spinal activity, these movements do not exclude the diagnosis of brain death. If the patient's family is to be at the bedside during either the apnea test or the withdrawal of mechanical ventilation, it is imperative that the clinicians prepare them for what they might see, so as not to alarm them with the fear that the diagnosis of brain death might have been in error.

Ventilator Withdrawal from Unconscious Patients Unlikely to Experience Distress. This prototype includes patients who are comatose but who are not brain dead. Although patients who are truly comatose are not capable of experiencing anything, in some cases there may be doubt about whether the patient has any rudimentary capacity for experiencing pain or suffering. In these cases, clinicians should err on the side of caution and provide an appropriate level of analgesia and sedation.

Withdrawal of life support usually can proceed rapidly in such cases, either by withdrawal of the artificial airway or by removing the mechanical ventilator. In either case, the patient may require anticipatory dosing with analgesics and/or sedatives and may require additional medication administered as necessary, titrated to the observed level of the patient's distress. Because some unconscious patients will not require the administration of any additional sedatives or analgesics, however, these should be given on an individualized basis according to need rather than dosed according to protocol (19).

Ventilator Withdrawal from the Conscious or Semiconscious Patient Likely to Experience Distress. This prototype includes patients who are definitely able to experience suffering, and the method of withdrawal needs to be tailored to minimize distress. In most cases, this will involve a more gradual withdrawal of both ventilator rate and supplemental oxygen. Although there is indirect evidence that patients may be more comfortable when supplemental oxygen is removed before ventilator rate (44), there are no clinical studies to support this approach. In any case, the gradual withdrawal of ventilator support allows clinicians the opportunity to carefully titrate sedatives and analgesics to the patient's level of comfort, thereby ensuring that the patient does not experience any treatable pain or suffering. Once the patient has lost consciousness from the combined effect of the medications and hypoxia, then the artificial airway can be removed.

In some cases, such as those involving patients with cervical quadriplegia or those undergoing advanced life support, the patient may prefer the rapid withdrawal of ventilation while sedated to a sufficient depth to eliminate any possibility of dyspnea or air hunger. This approach is also acceptable but requires very close attention to the adequacy of the anticipatory dosing to make sure that the patient does not experience acute suffering at the time of ventilator withdrawal. One technique for ensuring this is to use rapidly acting medications such as thiopental or propofol in sufficient doses to relieve the patient's suffering (66).

Special Issues in Communicating with Families Near the Time of Death

Notification of Death. Breaking bad news is one of the most difficult tasks that physicians face but is a common necessity in the practice of critical care medicine. Little empirical research on this topic exists to ground recommendations, however, and most suggestions are therefore based primarily on common sense, experience, and intuition. These deficiencies may explain in part why few clinicians have received formal training in how to deliver bad news. Even so, certain principles can be recommended (98–102). Bad news should be delivered in person, whenever possible. The ideal location is in a private room that has seating available for everyone. Clinicians should be attentive to their appearance, especially if they appear disheveled from performing a resuscitation or other work in the ICU. They should learn how to demonstrate compassion and empathy, by beginning with words of condolence, maintaining eye contact, and extending a comforting touch when appropriate. Although well-intended, clichés like "He's at peace now," or "At least she lived a long and happy life" should be avoided, because these are often not well received and can be seen as offensive.

Clinicians often inadvertently use unfamiliar jargon when talking with patients and families. Words such as *code*, *CPR*, and *vent* should be avoided in favor of more clearly understood terms such as *heart stopped*, *tried to start the heart*, and *breathing machine*. In particular, clinicians should not be afraid to use the words *died* and *death*; saying only that resuscitation was unsuccessful or that the patient expired will often risk misunderstanding (29). Development of these "bilingual" skills should be a priority for critical care clinicians.

The family frequently must be contacted by telephone if they are not present at the time of death. A Gallup poll of a sample of the U.S. adult population reported that when death of a family member was unexpected, most (64%) preferred to be told that the patient was

critically ill and to come to the hospital immediately (103). Only 26% preferred to be told over the telephone that the patient had died. These findings were mirrored in a companion survey of physician practices, which found that 72% of the physicians preferred to defer informing the family of the patient's death until the family arrived at the hospital, whereas only 25% would relay the information immediately over the telephone. These preferences changed dramatically, however, when the death of the patient was perceived as "expected." In these circumstances, only 13% of physicians would delay notification until the family's arrival, with 83% informing the family directly.

When the patient has been declared dead by neurologic criteria ("brain dead"), clinicians must be particularly careful with their words so as not to confuse the family. One of the most common mistakes is to say something like, "We have diagnosed your son as brain dead. He will die very quickly after he is removed from the ventilator." Patients are declared dead at the time that the requirements for brain death are met. This is the time that should appear on the death certificate as the time of death. Removal of the ventilator at a later time should be seen as the removal of unnecessary machines from a corpse. Although clinicians should be compassionate in the language that they use, they must take care to deliver an accurate and consistent message to the family and emphasize that bodily functions dependent on the brain are being artificially supported and will cease as soon as the machines are stopped. For example, a family could be told, "We tested your son and unfortunately we found that none of his brain is working. That means he is dead. He passed away at 6 o'clock."

Permission for Autopsy. Physicians may sometimes have the opportunity to discuss the option of an autopsy with the patient or family before death, particularly in situations where death is expected and the patient or family has had an opportunity to reflect on their wishes beforehand. In most cases, however, discussions about autopsy occur within a short time after the patient's death. Because this may coincide with the height of the family's grief, many families may be unable to cope with the complicated factors that must be considered in making this decision. This problem is compounded by the fact that education about the autopsy procedure is perceived as inadequate in many residency programs (104), creating the risk of misinforming the family about the nature of the autopsy and possible alternatives. One frequent misconception is that the organs (or most of the organs) are customarily returned to the body after they are examined. Another is that a limited autopsy (percutaneous biopsies or examination of a single organ, for example) is generally an acceptable substitute for a complete autopsy. Even although modern imaging and diagnostic tools have increased the accuracy of premortem diagnosis, complete autopsies continue to provide answers to unresolved clinical questions and frequently reveal major unexpected factors that contributed to the patient's death (105).

Clinicians must be aware of local regulations that require notification of the medical examiner after death. When required, the medical examiner has authority to perform an autopsy without permission from the family. Clinicians should strive to maintain a supportive relationship with the family by emphasizing the importance and necessity of medicolegal examinations and that the clinical team typically has no influence over the medical examiner's decision. Medical examiners may take religious reasons for opposing an autopsy into account in reaching their decision, but in most jurisdictions they are under no obligation to do so. The medical examiner may not reach a decision concerning an autopsy until several hours after a patient's death. Families should be informed that an evaluation by the medical examiner's office is pending so that they will not be surprised if the medical examiner chooses to perform the autopsy. This is especially important if the family would otherwise decide against having an autopsy performed, because they could feel betrayed if they believed that their wishes were being arbitrarily disregarded. A clinician might say, for example, "We will do everything possible to respect your wishes regarding an autopsy, but you should know that the medical examiner is authorized by law to perform an autopsy, if he or she believes it is important for legal purposes."

Organ Donation. Current federal regulations require all institutions receiving Medicare or Medicaid funds to have the appropriate individual ask the family of every deceased patient for permission to procure tissues and organs (106). This discussion should occur separately from notification of the patient's death, and Health Care Financing Administration regulations now require that the request be made by someone specially trained in asking for organ and tissue donation. Critical care practitioners who are interested in making these requests should therefore receive special training. Recently these federal regulations have been revised so that institutions are now required to contact the local organ procurement organization concerning any death or impending death. When appropriate, the organ procurement organization then sends a representative to the hospital to ensure that the family will be approached at the appropriate time by a professional skilled in presenting the option of organ donation and in accurately answering the family's questions and addressing their concerns. Studies have documented that this approach enhances the likelihood that families will be asked to donate and might increase the chance that they choose to donate (107).

Although families of patients who have been declared brain dead commonly are asked to grant permission for organ donation, patients declared dead by cardiopulmonary criteria (so-called non-heart-beating organ donors) can also sometimes be suitable donors. Non-heart-beating cadavers have always been possible donors of skin, bone, corneas, and heart valves, but recent protocols have expanded the opportunities for some of these patients to donate kidneys, livers, and rarely even lungs and hearts. These solid organ procurements are performed under protocols that call for life-sustaining treatments to be withdrawn (usually mechanical ventilation) under controlled conditions (usually in the operating room), with death declared by cardiac criteria following 2–5 mins of pulselessness. Alternatively, non-heart-beating organ donation can proceed after a failed attempt at resuscitation. The solid organs then are either removed immediately or preserved *in situ* by infusing cold organ preservation solution through vascular cannulae before removal. This approach requires strict adherence to many ethical and technical details, and the procedure should never be performed on an *ad hoc* basis without a prospectively developed institutional protocol (108, 109).

Attending Funerals. Opinions about whether clinicians should attend funerals vary widely. Although it would be quite impractical for an intensive care clinician to attend funerals of patients regularly,

attendance may be welcome and appropriate when there has been a long-standing relationship between the clinician and the patient or family. Even when there has only been a brief opportunity for the clinicians to become acquainted with the patient or family, family members may feel a profound attachment to the ICU clinicians, perhaps because of the intensity of the ICU experience. Attendance at the funeral in these circumstances may be highly valued by the family and could permit the clinician to release some of the grief and loss that is a part of working with critically ill and dying patients. Striking a balance between the need to maintain a healthy emotional distance from patients and families and yet avoiding a destructive emotional detachment is a difficult yet important challenge for ICU clinicians.

Bereavement Programs. The responsibilities of intensive care do not end when the patient is taken to the morgue. In addition to the issues about autopsy and organ donation outlined previously, families may need assistance with choosing a funeral home and with making preliminary arrangements for the disposition of the body. If a family has consented to an autopsy, the ICU should ensure that a physician (e.g., an intensivist, a subspecialist, or a primary physician) will notify the family and offer to meet with them as soon as results are available. By explicitly delegating this task to a specific clinician, the chances are reduced that this important follow-up will be overlooked. Specific processes should be in place to ensure rapid response to spiritual and psychological needs, as required by the Joint Commission on Accreditation of Healthcare Organizations. Bereavement programs can be structured to provide follow-up cards or notes to the family at set intervals (usually including the first anniversary) and can include sympathetic comments from nurses and doctors who were involved in the patient's care. Supplemental information such as booklets or bibliographies to provide guidance and contact with support groups also can be provided (110, 111).

Special Ethical Issues

Terminal Sedation. Terminal sedation is a term that has been used to describe the practice of sedating patients to the point of unconsciousness, as a last resort and when all other methods of controlling their suffering have failed. Typically, either benzodiazepines or barbiturates are used as sedatives, although propofol could also be useful for this purpose (112). Once unconscious, patients typically die of dehydration, starvation, or a complication of the treatment, with death usually occurring within several days (66, 113, 114).

This approach rarely is needed in the ICU environment, where patients sedated to the point of unconsciousness are generally dependent on mechanical ventilation, with death following the withdrawal of that life-sustaining therapy. Occasionally, however, ICU patients who are not receiving mechanical ventilation will require escalation of analgesics and sedatives to the point of unconsciousness.

Some have argued that terminal sedation is merely a covert form of euthanasia. Once the patient is unconscious, generally no attempt is made to restore the patient to consciousness, and medical nutrition and hydration are terminated. Others have defended terminal sedation under the rule of double effect (115). In addition, the U.S. Supreme Court implicitly endorsed the practice in two recent decisions concerning physician-assisted suicide, citing the technique as an alternative to physician-assisted suicide that could ensure, at least theoretically, that no patient should die with "untreatable" pain. At least in part because of this legal endorsement, terminal sedation has become more widely practiced, although it remains controversial (116–120).

Treating the Patient vs. Treating the Family. A standard principle in bioethics is that physicians should consider only the patient's best interests and defend those interests against the potentially competing demands of third parties. This view may be a bit naïve. The interests of patients almost always are interwoven with those of family members and other loved ones, and physicians are often in the position of choosing which interests should prevail. This should not be surprising when one considers that family members make sacrifices for one another daily in everyday life; why should it be any different when it comes to making medical decisions? This tendency is especially prominent in pediatrics, where pediatricians commonly see their role as "treating the family," placing the best interests of the child within the context of the family's resources and needs.

Attitudes about the proper role of the family's interests vary widely. Some view the family's wishes primarily as a conflict of interest that needs to be blocked. Others allow the families' wishes to enter into decision-making only with the explicit permission of the patient, whereas others see the patients' interests as being interdependent with those of the family and at times legitimately overridden by the needs of these others.

These issues take on a special significance at the end of life. Because the interests of the patient may be perceived as greatly diminished at this time, clinicians may be more likely to consider the needs of the family as more important. Consider, for example, the question of whether to perform a tracheostomy and initiate chronic ventilation for a severely demented elderly man who is primarily cared for by his daughter. Perhaps in this circumstance the needs and wishes of the daughter and her family should be considered along with the best interests of the patient.

Similar issues arise in the use of sedatives and analgesics at the end of life. Consider a patient who is near death and having "agonal" respirations. The family finds these very distressing, despite reassurances from the clinicians that the patient is unconscious and not experiencing any pain or suffering. Should the physician administer additional opioid to the patient, with the intention of making the patient appear more peaceful for the benefit of the family? Both of these examples present relatively common dilemmas that are not well addressed by the standard principles and paradigms that currently exist in bioethics.

The Pharmacologically Paralyzed Patient. Neuromuscular blocking agents (NMBAs) are required occasionally for the management of critically ill patients, primarily to facilitate the use of nonphysiologic ventilatory modes such as inverse-ratio ventilation and high-frequency oscillation. When a decision is made to withdraw ventilator support from a patient who is paralyzed by these agents, there is a question as to whether the effects of the medication need to be reversed or allowed to wear off before the ventilator is withdrawn.

This dilemma is not infrequent. For example, three of 33 patients (9%) in one study continued to receive NMBAs during the withdrawal of life support (68). One survey of physician members of SCCM reported that 6% have used NMBAs at the end of life at least occasionally (30), whereas another survey of pediatric intensive care specialists in the United

Kingdom reported that 12% would continue NMBAs during ventilator withdrawal (121).

NMBAs possess no sedative or analgesic activity and can provide no comfort to the patient when they are administered at the time of withdrawal of life support. Clinicians cannot plausibly maintain that their intention in administering these agents in these circumstances is to benefit the patient. Indeed, unless the patient is also treated with adequate sedation and analgesia, the NMBAs may mask the signs of acute air hunger associated with ventilator withdrawal, leaving the patient to endure the agony of suffocation in silence and isolation. Although it is true that families may be distressed while observing a dying family member, the best way to relieve their suffering is by reassuring them of the patient's comfort through the use of adequate sedation and analgesia.

The same considerations apply to most patients who are receiving NMBAs at the time that the decision to withdraw life support is made. In most cases, the effect of these agents can be reversed or allowed to wear off within a short period of time, allowing for the withdrawal of mechanical ventilation in the absence of the confounding effects of paralysis. As a general rule, therefore, pharmacologic paralysis should be avoided at the end of life.

Patients who have been receiving NMBAs chronically for management of their ventilatory failure occasionally can present a more difficult ethical dilemma. In some situations, restoration of neuromuscular function may not be possible for several days or even weeks, because of relative overdosage of the drug or the accumulation of active metabolites (122). When faced with this problem, the clinician must choose between withdrawal of the ventilator while the patient is paralyzed vs. continuation of life support well beyond the point at which the patient and family have determined that the burdens of such treatments outweigh the probable benefits. In this circumstance, it may be preferable to proceed with withdrawal of life support despite the continued presence of neuromuscular blockade. This recommendation is in accord with others who have commented on this issue (34, 123–125).

Before proceeding with the withdrawal of life support from a patient who is pharmacologically paralyzed, several issues must be carefully considered. First, the clinicians must be quite certain that the patient is truly dependent on ventilator support for survival. This is not always easy to do—8% of "terminally weaned" patients from one study survived to hospital discharge (93). If there is a small but significant chance that the patient could survive separation from the ventilator in the absence of the neuromuscular blockade, then the effects of the blockade must be eliminated before ventilator withdrawal.

Second, clinicians must be aware that neuromuscular blockade will significantly impair their ability to assess the patient's comfort. Paralyzed patients are unable to communicate any evidence of discomfort or distress during the process of withdrawal of life support. Autonomic signs such as hypertension and tachycardia are highly unreliable. The onus is on the clinicians to use medications in dosages sufficient to ensure the patient's comfort despite the absence of the usual behavioral clues to the patient's level of distress. This is certainly possible (it is done routinely by anesthesiologists caring for pharmacologically paralyzed patients during anesthesia and surgery), but it does require sufficient knowledge, skill, and experience on the part of the ICU clinicians.

Third, clinicians must balance the costs of waiting until the NMBAs can be reversed or wear off against the potential benefits. In addition to removing uncertainty about the prognosis and ensuring the availability of behavioral clues about the patient's comfort, waiting until neuromuscular function can be restored has the theoretical benefit of allowing the patient to interact with family members and other loved ones both before and during the process of withdrawing life support.

In summary, in certain cases of prolonged paralysis, it may be reasonable to proceed with removal of the ventilator provided the clinicians a) are highly certain that the patient could not survive separation from the ventilator; b) proceed with careful regard for the patient's comfort; and c) have concluded that the benefits of waiting for the return of neuromuscular function are not sufficient to outweigh the burdens.

Conclusions

The early years of critical care medicine were defined by remarkable discoveries and innovations that dramatically reduced the morbidity and mortality of disease. In recent years, critical care practitioners increasingly have recognized that our obligations to patients extend beyond our attempts to treat disease and include a commitment to providing patients with a dignified and tolerable death.

Recommendations such as these can only attempt to articulate practices that are based on sound ethical reasoning and that are consonant with current cultural and legal norms.

Meeting these obligations will require that intensive care clinicians learn how to operate within a new paradigm or model of care. In the curative model, the "medical indications" for diagnostic and therapeutic procedures are judged relevant to the contribution they make toward curing the patient. In the palliative model, however, these indications are judged relative to symptom relief, improved functional status, or the amelioration of emotional, psychological, or spiritual concerns. The former focuses on the treatment of diseases, the latter on the treatment of symptoms.

In this context, treatment of the patient's pain often becomes the highest priority. The notion of pain as the fifth vital sign is one way of signifying this importance. Critical care clinicians are in a unique position to affect this symptom. Not only are we expert in delivering medications to relieve suffering, but we also can provide leadership that will enhance our ability to provide palliative care in ways that go beyond medications. We should work toward developing a culture and physical environment in the ICU that enhance communication and facilitate the comfort of our patients.

Practical aspects of end-of-life care are inseparably wed to many intensely controversial ethical issues. Recommendations such as these can only attempt to articulate practices that are based on sound ethical reasoning and that are consonant with current cultural and legal

norms. These norms are not static and undoubtedly will change over the years. What is unlikely to change, however, is a basic commitment to the comfort and well-being of the patient, regardless of whether the hopes for cure are high or nonexistent. As Albert Schweitzer noted several decades ago, "We all must die. But that I can save him from days of torture that is what I feel as my great and ever new privilege. Pain is a more terrible lord of mankind than even death itself" (126).

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Attorneys For Plaintiff MICHAEL ANGELO MORALES

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

MICHAEL ANGELO MORALES, Plaintiff, v. RODERICK Q. HICKMAN, Secretary of the California Department of Corrections; STEVEN ORNOSKI, Warden, San Quentin State Prison, San Quentin, CA; and DOES 1 -50, Defendants.	Case No. C 06 219 (JF) **DECLARATION OF DAVID SENIOR** **Date: January 26, 2006** **Time: 2:00 PM** **Courtroom: 3**

I, David A. Senior, declare and state:

1. I am one of the three attorneys representing Plaintiff Michael Angelo Morales.

2. In late September 2005, I telephoned Supervising Deputy Attorney General Keith Borjon to inquire whether the parties could resolve this case. Mr. Borjon advised me that the decision to pursue an execution in this case was not made by the Attorney General's office, but by the San Joaquin County District Attorney, and that I should talk to the District Attorney.

3. I further inquired of Mr. Borjon as to what the Attorney General's intentions were with respect to setting an execution date for Mr. Morales in the event that his certiorari petition was not granted, in light of the certiorari petitions of Clarence Allen and Stanley Williams – which were also under consideration by the Supreme Court at the same time during the Court's summer session. Mr. Borjon advised me that if three executions were to take place, they would not be conducted at the same time, and that Mr. Morales's execution would not take place first. I inquired as to whose execution would be scheduled second, and Mr. Borjon advised me that he didn't know. I believe that he didn't think that the decision had been made yet.

4. I asked Mr. Borjon to advise me as soon as he learned whether Mr. Morales's execution would take place second or third, and when it would take place. He said he would let me know. Mr. Borjon never gave me any further advices on this topic.

5. On December 15, 2005 at 2:34 p.m., Nathan Barankin, Communications Director for Attorney General Bill Lockyer, issued a press release that stated as to Mr. Morales, *inter alia*: "the San Joaquin County District Attorney will ask the Ventura County Superior Court to set an execution date for February or March of 2006." I received a copy of this press release by e-mail from a reporter at the Sacramento Bee on December 19, 2005 at 11:45 a.m. At that time, I had not been given timely notice by the Superior Court Clerk of Ventura County of the public session at which the execution date would be set, as required by California Rule of Court 4.315. I advised the San Joaquin County District Attorney accordingly by letter dated December 22, 2005. Jim Willett, the San Joaquin

County District Attorney, agreed to reset the execution-setting date during my telephone conversation with him later that day.

6. During my December 22, 2005 telephone conversation with Jim Willett (in the mid/late afternoon), I advised him of Mr. Borjon's advices to me that it was Mr. Willett's decision whether to pursue the execution of Mr. Morales. I requested an opportunity to discuss the matter with him. Mr. Willett stated that he had considered the matter already, but would be willing to discuss with me before making his final decision the propriety of proceeding with the execution. Mr. Willett mentioned that he was in the process of leaving the office to finish some Christmasshopping, and I suggested that I call him after Christmas so we would have time to discuss the matter fully. Mr. Willett stated that would be fine.

7. As of December 22, 2005, it still was unclear to me as counsel for Mr. Morales whether Mr. Willett would be willing to resolve this case without pursuing an execution. There were many reasons for Mr. Willett to consider doing so, including: (1) the numerous acts of prosecutorial misconduct committed by his office (before Mr. Willett was the District Attorney) in pursuing this and other capital sentences in the early 1980s [*see, e.g., Hayes v. Brown*, 399 F.3d 972 (9th Cir. 2005) (en banc) (granting new trial based on San Joaquin County prosecutor's elicitation of false testimony during a 1981 capital trial); *Belmontes v. Brown*, 414 F.3d 1094, 1115 (9th Cir. 2005) (San Joaquin County prosecutor violated obligation to "correct the false testimony and elicit the truth" regarding government favors to informant in capital trial arising out of 1981 homicide)] and (2) Mr. Willett's appointment of Craig Holmes, Mr. Morales's trial counsel, as his principal assistant in the San Joaquin County District Attorney's office and the concomitant conflict of interest which resulted.

8. In light of Mr. Willett's advices to me on December 22, 2005 that he would discuss the matter with me before making his final decision whether to proceed with this execution, it was not

reasonably clear to me in March 2005 – as the Attorney General suggests – that Mr. Willett intended to so proceed. Moreover, upon information and belief, Mr. Willett– the decision maker who is pursuing this execution– was not even the District Attorney in San Joaquin County in March 2005.

9. On December 23, 2005 at 10:56 a.m., I received a voice message from Chuck Schultz, a Deputy District Attorney in the San Joaquin County District Attorney's office, stating:

> Hello Mr. Senior, my name is Chuck Schultz I'm a deputy DA up in San Joaquin County calling you on Michael Morales. Uh, we are, and thank you for your call yesterday to uh our boss uh we did send it to the wrong address. It was uh a notice you wrong. Uh uh we're gonna correct that, we're gonna re-notice this thing for, in all likelihood January 10th of 19 of uh 06. Uh uh if that changes I'll let you know. Uh and uh thank you very much and have a happy holidays. Bye bye.

10. Mr. Schultz's office neither re-noticed the execution date for January 10, 2006 nor advised me of a change in the date (as Mr. Schultz advisedhe would in his December 23 message).

11. On January 5, 2006, I called Mr. Willett again to set up the meeting to discuss whether he was willing to resolve this case short of an execution. I left a voice message requesting that he return my call. He never did.

12. On January 9, 2006, I received a Notice of Public Session scheduling the execution-setting dateon January 18, 2006, for an execution to take place on February 21, 2006.

13. On January 11, 2006, I sent a letter to Mr. Willett by fax and e-mail stating, *inter alia*: "I have made efforts to discuss this decision with Mr. Willet by telephone on December 22, 2005. Mr. Willet agreed to discuss the matter further, and I called him again on January 5, 2006, leaving a message requesting that he return my call. Please know that I wish to discuss this further with you." Again, Mr. Willett did not return my call. I telephoned Mr. Willett again to discuss the matter on January 11, 2006 at 9:58 a.m. Again I left Mr. Willett a message to return my call. He never did so.

14. On January 12, 2006, in response to Mr. Morales's ex parte application– which was made with timely notice to Mr. Willett – the Superior Court entered an order continuing thepublic session to January 31, 2006 to allow Mr. Morales to move to disqualify the District Attorney and strike the Notice of Public Session because Mr. Morales's trial counsel, Craig Holmes, is now the Assistant District Attorney of San Joaquin County and Mr. Holmes's office was seeking an execution date against his former client, Mr. Morales.

15. On January 17, 2006, pursuant to an untimely and improperly noticed ex parte application by the Attorney General's office, the Superior Court vacated its January 12, 2006 order and advanced the execution-setting date to January 18, 2006, at 1:30 p.m.. It further ordered, however, that Mr. Morales's Motion to Disqualify the District Attorney and Strike the Notice of Public Session be heard on January 18, 2006, immediately before the execution setting hearing (if any) took place.

16. On January 18, 2006 at 1:30 p.m., without regard to the Superior Court's order entered the previous day that Mr. Morales's Motion to Disqualify the District Attorney and Strike the Notice of Public Session be heard before the public session to set the execution date, a different Superior Court department proceeded– at the demand of the Attorney General – to set the execution date for February 21, 2006, without having a hearing on Mr. Morales's motion to disqualify the District Attorney and Strike the Notice of Public Session.

I declare under penalty of perjury under the laws of the state of California and the United States of America that the foregoing is true and correct. Executed this 24th day of January 2006 in San Francisco, California.

By: _____

David Senior

UNITED STATES DISTRICT COURT
JUDGE JEREMY FOGEL, PRESIDING
COURTROOM NO. 3 - 5TH FLOOR

CIVIL MINUTES

Court Proceedings:: Law and Motion Hearing, Thursday, January 26, 2006
Case Number: CV-06-219-JF/HRL

Courtroom Deputy Clerk: Diana Munz
Court Reporter: Peter Torreano

TITLE: **MICHAEL A. MORALES V. RODERICK Q. HICKMAN, ET AL**

PLAINTIFF	**DEFENDANT**
Michael Morales	**Roderick Q. Hickman**
Attorneys Present: John Grele, David Senior	**Attorneys Present: Dane Gillette**

PROCEEDINGS:

Hearing on Motion for Temporary Restraining Order and Motion for Discovery held. Counsel are present.

Court sets the case for Preliminary Injunction hearing on February 9, 2006 at 2:00 p.m.

Counsel are directed to provide discovery requests to the Court by the end of the day on January 27, 2006 and to file one additional brief by 5:00 p.m. on February 6, 2006.

JOHN R GRELE
Attorney at Law
703 Market Street, Suite 550
San Francisco, CA 94103
Telephone: 415-348-9300 Facsimile: 415-348-0364

January 27, 2006

Dane Gillette
Senior Assistant Attorney General
455 Golden Gate Avenue, suite 1100
San Francisco, CA 94102

Via electronic mail

Re: *Morales v. Hickman*
United States District Court docket no. 06-219 (JF)

Dear Mr. Gillette:

Pursuant to the Court's instructions yesterday, and the questions that were raised in the hearing, we are providing you with the request for the following:

Document Requests

1. All items listed in our Motion for Expedited Discovery.

2. The name, qualifications, training, descriptions of tasks, including equipment used, for the person(s) who determine when an inmate is unconscious for the purposes of lethal injection

3. The name, qualifications, training, and descriptions of tasks for the person(s) who determine when to deviate from Procedure 770, and how.

4. Any documents or evidence pertaining to whether CDC has seen seizures or writhing during any executions; documents on the decision to include pancuronium in the lethal injection process.

5. Documents reflecting any occasions on which the injection team has deviated from the protocol, including but not limited to the administration of second doses of potassium chloride.

6. Any documents concerning attempts to investigate why the second dose of potassium was necessary, whether it was normal or harmful, and means of correcting for it.

7. Any other documents or evidence besides the execution logs that describes what occurred during any executions, including any videotapes or voice recordings.

Interrogatory Requests

8. Identification of the persons, whether current employees or not, who:

Are responsible for collecting and maintaining documents pertaining to lethal injection ;
Were responsible for or contributed to the proposing, devising and/or modifying the qualifications, experience and training of lethal injection personnel;
Were responsible for monitoring of the lethal injection process during executions;
Were responsible for determination of unconsciousness in executions;
Were responsible for or contributed to the creating, proposing, and devising of procedure 770 (and revisions); and,
Has conducted or contributed to a medical, ethical or other expert evaluation of the chemicals used, qualifications and training of personal involved, and the procedures employed in Procedure 770 (and revisions).

Deposition Requests

In addition, we are requesting the following depositions:

9. Doctor St. Clair;

10. Person(s) most knowledgeable regarding the following:

documents pertaining to lethal injection ;
qualifications, experience and training of lethal injection personnel;
monitoring of the lethal injection procedure;
determination of unconsciousness;
adoption (and revisions) of 770;
medical, ethical and other expert evaluation of 770 (and revisions).

11. Previous doctors attending executions.

Sincerely yours,

/s/
John R Grele

BILL LOCKYER
Attorney General

State of California
DEPARTMENT OF JUSTICE

455 GOLDEN GATE AVENUE, SUITE 11000
SAN FRANCISCO, CA 94102-7004

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January 27, 2006

John R. Grele
703 Market Street, Suite 550
San Francisco, CA 94103

RE: Morales v. Hickman
C 06-219 JF

Dear Mr. Grele:

This is in response to today's letter requesting discovery and the earlier motion for expedited discovery incorporated in your letter. In most instances there are no documents responsive to your requests, including in particular items 4, 5, 6, and 7 of your document request in the letter.

The issue of what if any portion of the unredacted 770 protocol will be disclosed is already before the district court.

Any changes to the protocol are incorporated in the current version. Protocol 770 is the complete procedure for conducting a lethal injection execution.

With respect to the development of the lethal injection protocol, there are copies of protocols from other states that were obtained and reviewed by California. Should the court deem them relevant they will be provided pursuant to an order.

The decision to implement lethal injection as an alternative method of execution was made by the Legislature and that determination is not at issue in the present litigation. I am not aware of any documents in possession of defendants relevant to that request.

The "Execution Security Plan" is an internal document and will not be disclosed.

Defendants will not disclose the names of any member of the execution team or other participants in the execution process, and will so assert in response to interrogatory or deposition requests.

An electrocardiogram machine is used to monitor the inmate's heart during the execution. There are no documents relating to its use other than what is in the protocol.

There are no documents relating to the drugs used and their preparation other than what is in the protocol.

There are no provisions for reviving an inmate once an execution has begun.

Execution medical logs of all lethal injection executions have been disclosed or are already in plaintiff's possession except for the Thompson execution. Prison officials have been unable to locate that log.

Other than the logs there are no documents describing past executions. There are no autopsy, toxicology, or any other blood reports as such examinations are not performed after the execution. No photographs are taken during the execution.

Sincerely,

DANE R. GILLETTE
Senior Assistant Attorney General

For BILL LOCKYER
Attorney General

JOHN R GRELE
Attorney at Law
703 Market Street, Suite 550
San Francisco, CA 94103
Telephone: 415-348-9300 Facsimile: 415-348-0364

January 27, 2006

Dane Gillette
Senior Assistant Attorney General
455 Golden Gate Avenue, suite 1100
San Francisco, CA 94102

Via electronic mail

Re: *Morales v. Hickman*
United States District Court docket no. 06-219 (JF)

Dear Mr. Gillette:

From your response, it appears the only documents regarding lethal injection, executions and the establishment and revision of 770 that CDCR admits it possesses are the current version of 770, the Execution Security Plan, the EKGs, the logs and the protocols from other states. And, no recordings of any kind have been made. Is this accurate? Will they turn over the EKGs?

The response indicates that there are no documents relating to certain issues "other than what is in the protocol." Does this mean that there are no documents other than Procedure 770 itself? If not, what is your position on us obtaining the documents that are mentioned or described in the protocol? And, when you state "other than the protocol", is it the protocol as redacted or is it the one submitted under seal, or both?

Does CDCR possess the previous versions or drafts of 770? The response says all changes are in the current 770, but we requested all versions.

I would appreciate your responses to these inquires as your response so far is somewhat unclear.

Sincerely yours,

/s/
John R Grele

BILL LOCKYER
Attorney General

State of California
DEPARTMENT OF JUSTICE

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January 27, 2006

John R. Grele
703 Market Street, Suite 550
San Francisco, CA 94103

RE: Morales v. Hickman
C 06-219 JF

Dear Mr. Grele:

This is in response to your second letter of January 27, 2006.

Your first paragraph is accurate. There are EKG tapes from some if not all of the lethal injection executions. You may review them at the prison. There are no other recordings of any sort.

There is no document other than I.P. 770 which sets forth the procedures to be followed in a lethal injection execution. Absent a court order the documents referenced in the protocol will not be disclosed.

There are some prior versions of 770. Defendants will make them available..

Sincerely,

DANE R. GILLETTE
Senior Assistant Attorney General

For BILL LOCKYER
Attorney General

STATE OF CALIFORNIA
DEPARTMENT OF CORRECTIONS AND REHABILITATION
INMATE APPEALS BRANCH
P. O. BOX 942883
SACRAMENTO, CA 94283-0001

DIRECTOR'S LEVEL APPEAL DECISION

Date: **EMERGENCY**

In re: Morales, C-68801
California State Prison, San Quentin
San Quentin, CA 94964

IAB Case No.: 0507508 Local Log No.: SQ 06-78

This matter was reviewed on behalf of the Director of the California Department of Corrections and Rehabilitation (CDCR) by Appeals Examiner P. Enriquez, Facility Captain. All submitted documentation and supporting arguments of the parties have been considered.

I APPELLANT'S ARGUMENT: It is the appellant's position that his execution by lethal injection is imminent and will be a cruel and unusual form of punishment. The lethal injection protocol does not use medically proper and approved procedures. The use of lethal injection will cause pain and torture. The appellant has grave concerns that he will be conscious and not properly sedated and anesthetized because of the drugs and the ways they are given are flawed. The use of pancuronium bromide may cause paralysis and suffocation so he cannot speak if something is wrong and will cause unnecessary pain. None of the drugs are acceptable. The prison and protocol does not provide for properly trained and qualified personnel or any minimum qualifications for personnel who will know how to insert an IV or administer any of the chemicals. The protocol does not provide for medical people to be present and help out in the event of complications.

The appellant requests that he not be executed until these problems are fixed and the method of execution is employed with proper procedures, that the medical supervisor use trained, competent, and qualified personnel according to a proper protocol, that the protocol be rewritten, and that personnel be trained.

II SECOND LEVEL'S DECISION: The reviewer found that the appellant's claim regarding problems he perceives with California's lethal injection procedures are based solely upon his own information and belief. The appellant provides neither empirical evidence nor any scientific study that would support his claims. Should the appellant not select a method of execution within ten (10) days after service of an execution warrant, California Penal Code Section (PC) 3604(b) provides that the penalty of death shall be imposed by lethal injection. Based upon the submitted documentation from the appellant, as well as the conducted interview, the findings are that the appellant's issues have been appropriately addressed and duly responded to by the Second Level of Review (SLR). The reviewer's findings are that the appellant's contentions are unsupportable and therefore, are without merit.

III DIRECTOR'S LEVEL DECISION: Appeal is denied.

A. FINDINGS: The SLR has properly reviewed and considered the appellant's appeal issues. The appellant has failed to provide any substantive evidence that would lend credibility to his claim that he will experience pain and torture if executed by lethal injection. The appellant has requested that the method of execution (lethal injection) be employed with proper procedures and medical supervision using trained, competent, and qualified personnel. The appellant is advised that the staff who participate in the execution process receive continuous training, are competent, and follow established execution protocol as defined in California State Prison, San Quentin CDC Operations Manual Supplement #770. The appellant does have the option of choosing execution by lethal gas as an alternative to lethal injection. Whereas the appellant's sentence and penalty were legally established by court decision in the State of California, no further relief shall be afforded the appellant at the Director's Level of Review.

B. BASIS FOR THE DECISION:
PC: 3604
California Code of Regulations, Title 15, Section: 3349

C. ORDER: No changes or modifications are required by the institution.

This decision exhausts the administrative remedy available to the appellant within CDCR.

N. GRANNIS, Chief
Inmate Appeals Branch

cc: Warden, SQ
Appeals Coordinator, SQ

E-filed 2/1/06

UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

Michael Angelo MORALES, Plaintiff, v. Roderick Q. HICKMAN, Secretary of the California Department of Corrections and Rehabilitation; Steven W. Ornoksi, Acting Warden of San Quentin State Prison; and Does 1-50, Defendants.	Case Number C 06 219 JF DEATH-PENALTY CASE ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFF'S MOTION FOR EXPEDITED DISCOVERY [Docket Nos. 6 & 27]

Plaintiff is scheduled to be executed on Tuesday, February 21, 2006. He seeks expedited discovery in the present action, which challenges California's lethal-injection protocol. The Court has read the moving and responding papers and has considered the oral arguments of counsel presented on Thursday, January 26, 2006.

In connection with the hearing on Plaintiff's motion for a preliminary injunction to be heard on Thursday, February 9, 2006, and good cause appearing therefor, Defendants shall, within forty-eight (48) hours after this Order is filed, produce to Plaintiff the documents identified in the following Document Requests itemized in Plaintiff's filing dated January 27, 2006, to the extent that such documents relate to the executions of Donald J. Beardslee, Stanley Tookie Williams or Clarence Ray Allen: 1, 9, 14, 15, 22, 26, 27, 29, 31, 36 and 37. Defendants

may redact the names of executioners from any documents produced pursuant to this Order. Plaintiff's remaining discovery requests are denied without prejudice; they may be reconsidered should the Court decide to grant a stay of execution.

The Court has reviewed in camera San Quentin Institution Procedure No. 770, the confidential, unredacted version of California's lethal-injection protocol, and has compared it to San Quentin Operational Procedure No. 770, the redacted version of the protocol that Defendants already have made available to Plaintiff. The Court having weighed Plaintiff's showing of good cause for disclosure against Defendants' legitimate concerns about security, Defendants shall, within twelve (12) hours after this Order is filed, produce to Plaintiff and e-lodge with the Court (via e-mail to g_o_kolombatovich@cand.uscourts.gov) San Quentin Institution Procedure No. 770, subject to the following redactions and modifications:

(1) Sections VI.A.1.d.3), VI.A.1.d.4),VI.A.1.d.6),VI.A.1.f.,VI.A.4.a.,VI.A.5., VI.A.6., VI.A.9.a. and VI.A.9.d. may be produced as presently redacted;

(2) Section VI.A.9.f. may be deleted;

(3) Section VI.A.9.g. may be produced in the same form as § VI.A.9.f. of the redacted protocol;

(4) Sections VI.A.10.a.2) andVI.A.10.b. may be produced as presently redacted;

(5) Section VI.A.10.d.3) may be deleted;

(6) Section VI.A.10.d.4) may be produced in the same form as § VI.A.10.d.3) of the redacted protocol;

(7) Sections VI.A.10.e.1) and VI.A.10.e.3) may be produced as presently redacted;

(8) Section VI.B.5. may be produced in the same form as the first section designated § VI.B.6. in the redacted protocol;

(9) Sections VI.B.6.a. and VI.B.6.b. may be produced in the same form as the second section designated § VI.B.6. in the redacted protocol (§§ VI.B.6.c. and VI.B.6.d. shall be disclosed without redactions);

(10) Section VI.B.7. may be produced as presently redacted;

(11) Section VI.C. may be deleted;

E.R. 0230

(12) Section VI.D. may be produced as presently redacted;

(13) Section VI.E. may be deleted;

(14) Section VI.F.1.b.10) may be produced in the same form as § VI.E.1.a.10) in the redacted protocol;

(15) Section VI.F.2.b. and the sentence regarding keys in § VI.F.4.d.3)(a) may be deleted;

(16) Section VI.F.4.d.4) may be produced in the same form as § VI.E.4.d.4) appears in the redacted protocol;

(17) Section VI.F.4.d.5)(b)(1) may be produced in the same form as § VI.E.4.d.5)(b)(1) of the redacted protocol (§§ VI.F.4.d.5)(b)(2) and VI.F.4.d.5)(b)(3) shall be disclosed without redactions);

(18) The telephone number in § VI.F.4.d.5)(c) may be deleted.

All documents or parts thereof produced pursuant to this Order shall remain confidential. They may be revealed to and used by only Plaintiff's attorneys and experts; disclosure shall not be made to any other persons or organizations without the Court's prior authorization. In the event that a party wishes to submit to the Court any briefs or other materials that disclose or tend to disclose the contents of any document or part thereof produced pursuant to this Order, the party shall do so under seal via e-mail to g_o_kolombatovich@cand.uscourts.gov. However, copies of such briefs or other materials shall be e-filed in the public record with the confidential contents and references thereto deleted, and such deletion shall be noted as having been made pursuant to this Order.

Unless otherwise ordered by the Court, the confidentiality provisions of this Order shall continue in effect even after the conclusion of the present action.

IT IS SO ORDERED.

DATED: February 1, 2006

JEREMY FOGEL
United States District Judge

E.R. 0231

DECLARATION OF MARK DERSHWITZ, M.D., Ph.D.

I, Mark Dershwitz, M.D., Ph.D., hereby declare as follows:

1. I am a physician and also have a Ph.D. in pharmacology. A true and accurate copy of my curriculum vitae is attached as Exhibit A. I am licensed to practice medicine in the states of Massachusetts and Maine. I am currently an anesthesiologist at the University of Massachusetts and I am certified by the American Board of Anesthesiology. I am currently Professor of Anesthesiology and Biochemistry and Molecular Pharmacology at the University of Massachusetts.

2. I have done extensive research and written numerous review articles and research papers on the use of anesthetics and I regularly practice medicine in that capacity. My research includes the study of the pharmacodynamics and the pharmacokinetics of drugs. Pharmacokinetics is the study of the time course of a drug, while pharmacodynamics refers to the effects of a drug.

3. Prior to my current appointment at the University of Massachusetts, I have been an Instructor, Assistant Professor and Associate Professor at Harvard Medical School. I have testified as an expert witness concerning the pharmacokinetics and/or pharmacodynamics of anesthetic medications and other medications. I have testified in court as an expert witness on eleven occasions. I have given eighteen depositions as an expert witness.

4. At the request of the California Attorney General I rendered an expert opinion in the Kevin Cooper litigation with respect to California's procedures for executing condemned prisoners by lethal injection. A copy of that declaration is attached as Exhibit B. I reaffirm the opinions in that declaration.

5. An article published by Leonidas Koniaris and others entitled, "Inadequate anaesthesia in lethal injection for execution," was published in April, 2005 in The Lancet. A copy is attached as Exhibit C. The article quoted blood thiopental concentrations obtained at the autopsies of inmates executed by lethal injection and the authors stated, "we suggest that it is possible that some these inmates were fully aware during their executions." In subsequent issues of The Lancet, a number of letters to the editor criticized the flawed methodology of this study

and cast doubt on the authors' conclusions. Specifically, the correspondents suggested that blood samples obtained hours after death might contain concentrations of the medications that were not reflective of those which were present at the time of death. Certainly other classes of medications undergo a process called postmortem redistribution in which the blood concentration of a drug continues to change, either upward or downward, after death. Up through 2005, however, there were no rigorous scientific studies on the propensity for thiopental to undergo postmortem redistribution.

6. On May 13, 2005, the state of Connecticut executed inmate Michael Ross. The state medical examiner, Dr. H. Wayne Carver, obtained a blood sample from the inmate's femoral vein within a few minutes of the pronouncement of death. Analysis of this blood sample revealed a thiopental concentration of 29.6 mg/dL, a concentration associated with a probability of consciousness of approximately 0.001%. Dr. Carver performed an autopsy approximately seven hours later and obtained another blood sample from the femoral vein. This second blood sample contained thiopental at a concentration of 9.4 mg/dL. If this concentration were used to predict the probability of consciousness, the erroneous conclusion would have been that the inmate had approximately a 10% chance of being conscious throughout the execution. A copy of the autopsy report is attached as Exhibit D.

7. Although these data are from just one execution, they are compelling in suggesting that postmortem redistribution does indeed occur with thiopental, and it occurs in the direction of decreasing blood concentrations as a function of the time after death at which the blood sample is obtained. Furthermore, these data provide an explanation for the many low thiopental concentrations obtained at autopsy and referenced in the aforementioned journal article.

8. I have reviewed the execution logs of inmates executed by lethal injection in California. In several of these logs, the elapsed time between the beginning of thiopental administration and cessation of breathing is reported as up to five minutes. Because cessation of breathing was determined by remotely observing the inmate, the actual time was almost certainly less.

9. California uses a dose of 5000 mg of thiopental in its lethal injection protocol. In contrast, the usual dose used at the beginning of a general anesthetic for surgery is 300- 400 mg. All of the standard textbooks in anesthesiology state that following a dose of 300-400 mg of thiopental, breathing will cease within a minute, and the patient will remain apneic (without breathing) for about five minutes. The apparent disparity is dependent upon the method by which breathing is assessed.

10. In the operating room, anesthesiologists use two highly sensitive monitoring devices to measure breathing. One measures the volume of each breath in mL, while the other measures the amount of carbon dioxide in the exhaled gas. Using these sensitive monitors to assess breathing, patients do indeed stop breathing within a minute of receiving a does of thiopental. The duration of apnea depends upon the total dose of thiopental; the larger the dose, the longer the duration of apnea.

11. Despite the presence of apnea, the patient's (or inmate's) chest wall may move. This movement is not associated with the coordinated muscle contractions involved in breathing, however it may be misperceived as breathing by an observer relying on visual inspection alone. The presence or absence of these chest wall movements following thiopental administration is not associated in any way with the likelihood of consciousness or unconsciousness.

Executed under penalty of perjury under the laws of the United States, on this 2nd day of February, 2006, at Worcester, Massachusetts.

Dated: February 2, 2006

MARK DERSHWITZ, M.D., Ph.D.

United States Court of Appeals

for the eighth circuit

06-1379

Michael Anthony Taylor,	*	
	*	
Appellant,	*	Appeal from the United States
	*	District Court for the
v.	*	Western District of Missouri
	*	
Larry Crawford, Director, Missouri Department of Corrections, James D. Purkett, Superintendent, Eastern Reception Diagnostic & Correction Center and John Does, 1-666 (Anonymous Executioners),	*	
	*	
	*	
	*	
Appellees.		

FILED: February 1, 2006

Before LOKEN, Chief Judge, WOLLMAN, ARNOLD, MURPHY, BYE, RILEY, MELLOY, SMITH, COLLOTON, GRUENDER, and BENTON, Circuit Judges.

ORDER

Appellant Michael Anthony Taylor's petition for rehearing en banc is granted. Appellant's application for a stay of execution is granted.

Judge Riley would deny the petition and deny the application for a stay.

Judge Benton took no part in the vote in this matter.

Order Entered at the Direction of the Court.

Michael E. Gans
Clerk of Court

United States Court of Appeals for the Eighth Circuit.

DECLARATION OF SRIKUMARAN (SRI) K. MELETHIL, PH.D., J.D.

Srikumaran (Sri) K. Melethil, Ph.D., J.D., declares under penalty of perjury as follows:

1. My name is Srikumaran (Sri) K. Melethil, Ph.D., J.D. I am a pharmacokineticist. My curriculum vitae is attached to this declaration. Pharmacokinetics is the science of how drugs act in the body over time.

2. On September 19, 2005, I was contacted by Elizabeth Unger Carlyle, an attorney in Lee's Summit, Missouri. She explained to me that she represented an intervenor plaintiff, Richard Clay, in a U.S. District Court case involving Missouri's lethal injection procedure. She sought my expert testimony in connection with that case. I agreed to help.

3. Over the past several months, Ms. Carlyle and I have conferred several times about the issues in the case and the need for discovery as to the conclusions of the state's expert.

4. On January 18, 2006, Ms. Carlyle contacted me by e-mail and told me that a hearing date on the case might be imminent; she asked for and was given my conflict dates.

5. On January 26, 2006,, Ms. Carlyle contacted me again. She informed me that a merits hearing was scheduled for February 21-22, and that my testimony likely would be needed on February 21.

6. On January 30, 2006, Ms. Carlyle attempted to contact me by telephone and e-mail to inform me of the immediate hearing in the case. Because I was traveling, I did not receive these communications until Tuesday, January 31, 2006. I spoke with her that day.

7. I have reviewed the testimony and affidavits of Dr. Mark Dershwitz, the state's expert in this case, which was presented in the case of Timothy Johnston. For the purposes of this declaration, I am assuming that his testimony in Mr. Taylor's case was similar.

8. Dr. Dershwitz has indicated, based in part on a graph which he presented, that the blood level of sodium thiopental which would be present in the executed prisoner's blood at the time of death was sufficiently high that the prisoner would become unconscious shortly after the administration of sodium thiopental and would remain unconscious until death. Dr. Dershwitz has not, to my knowledge, provided the data on

which he bases this conclusion. My own study of the area reveals no data supporting this conclusion.

9. The level of the drug in the brain, rather than that in the blood, determines whether a person will be unconscious. Dr. Dershwitz presents no data about measured brain levels of thiopental, either in humans or in laboratory animals. (For obvious reasons, it is impossible to determine the brain level of thiopental in a living human.)

10. Attached to this declaration is a graph showing the decline in the level of sodium thiopental in laboratory rats over time. The graph indicates that the decline is quite rapid. This is no surprise, because one of the reasons sodium thiopental is used clinically is that it wears off quickly. This characteristic decline in brain levels makes me suspicious that Dr. Dershwitz's conclusions about consciousness and blood levels may be inaccurate.

11. Because I still do not know what data Dr. Dershwitz used, I cannot now express an opinion to a reasonable degree of scientific certainty

about his conclusions. However, if I had access to his data, I would be able to do so.

12. Goodman & Gilman's, *The Pharmacological Basis of Therepeutics*, 9th Ed., a standard reference in pharmacology, notes that in surgical situations, the dosage of sodium thiopental needed for sedation varies with the person. Some people need larger doses than others. At p. 323, the reference notes, "Patients who require a large initial dose of thiopental will awaken despite plasma concentrations that normally would cause sleep." Based on this reference, it is my opinion that blood levels of thiopental are not necessarily determinative of whether a particular person will actually be asleep during a procedure. Thus, I believe that the issue of whether persons subjected to the Missouri protocol will suffer unnecessarily due to the failure of anesthesia deserves further study.

Signed under penalty of perjury this 1st day of February, 2006.

Srikumaran (Sri) K. Melethil, Ph.D., J.D.

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Attorneys For Plaintiff MICHAEL ANGELO MORALES

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

MICHAEL ANGELO MORALES, Plaintiff, v. RODERICK Q. HICKMAN, Secretary of the California Department of Corrections; STEVEN ORNOSKI, Warden, San Quentin State Prison, San Quentin, CA; and DOES 1-50, Defendants.	Case No. C 06 219 (JF) **THIRD DECLARATION OF DR. MARK HEATH** **SUBMITTED UNDER SEAL Pursuant to Court Order** **Date: February 9, 2006** **Time: 2 pm** **Courtroom: 3**

Dr. Mark Heath, under penalty of perjury, both deposes and states as follows:

1. I have reviewed the documents produced pursuant to the Court's discovery order and the version of Procedure No. 770 produced and redacted pursuant to the Court's order. I would like to note for the record that this affidavit had been prepared in haste due to the limited time available and due to other work obligations that I am under.

A. Assessing the Risk of Inadequate Anesthesia

2. The California Department of Corrections and Rehabilitation's manner of conducting executions and the nature of the execution process has rendered it impossible to quantify precisely the risk of inadequate anesthesia for an individual inmate. In the clinical setting the primary way to determine whether a person was inadequately anesthetized during a surgical procedure is to ask him or her after he or she has emerged from the anesthetic. This is impossible with executed inmates. Another possible means of inferring anesthetic depth is to measure blood levels of the intravenous anesthetic that was used. However, California has not provided toxicological data, and has thereby closed off this avenue of inquiry. Yet another possible means of assessing anesthetic depth is to observe the physical behavior and movements of the person being executed. However, by choosing to administer pancuronium the CDCR has made it very difficult to rely on this method. Examination of execution logs and recorded data, as well as discussions with the individuals who were present, are thus the only means available for discerning whether past executions have been humane or inhumane.

3. What I do know, however, is that the CDCR has designed an execution procedure that falls well short of the standards widely considered acceptable for euthanizing animals. Procedure No. 770 renders errors in setting up the equipment and administering the drugs highly likely by deviating from accepted medical practice of the administration of intravenous anesthesia, which is designed specifically to prevent foreseeable errors. The protocol does not provide any guidance to the injection team in its exercise of discretion should errors or accidents occur. Indeed, most importantly, the protocol makes it impossible to detect errors or inadequate anesthesia by requiring remote administration and failing to provide for any assessment of anesthetic depth and by failing to

include supervising and/or participating personnel who are trained in the assessment of anesthetic depth.

4. The nature of complex medical procedures is such that even an ideal protocol designed by fully qualified individuals cannot obviate the possibility that unanticipated events may occur, forcing the injection team to react. This is why it is crucial that the injection team have the medical training necessary to enable them to take the steps necessary to ensure a humane execution despite unforeseen events. I have seen no evidence that CDCR's injection personnel are trained in any manner or qualified to set up the equipment, administer the drugs, or assess anesthetic depth. The CDCR's silence concerning the training and qualifications of the injection team, the warden, and other officials responsible for designing and maintaining the protocol heightens my concern that indeed the qualifications are insufficient. Notably, many other states have provided detailed information about the qualifications, training, background, and credentials of the execution team personnel.

5. The execution logs and other records provided in discovery reveal that the CDCR has deviated from its procedures several times on an ad hoc basis – by giving a second dose of potassium chloride and a second dose of pancuronium – without explanation or any apparent attempt to investigate or modify the protocol or its procedures so that such issues will not arise again. As described above, an unforeseen event may force a deviation from the protocol. After one such event, and certainly after three or four, medical standards require the CDCR to investigate whether and how it should modify the protocol. Such modification should be accomplished in a considered manner, after discussion, and consultation with appropriate experts. The CDCR's apparent disregard for the need to evolve its protocol, its repeated failure to follow its own protocol, and the casual attitude with which the warden discusses deviations from the protocol, together portray an unprofessional and unacceptable environment that needlessly amplifies the risk of an inhumane execution.

6. Finally, as discussed below, the execution logs and other records indicate that on several occasions, the inmates have continued breathing for several minutes after the administration of the thiopental, in one case, until the potassium was administered. This is not consistent with the

successful administration of 5 grams of thiopental, and absent any alternative explanation by the execution team personnel, leaves only the conclusion that the thiopental dose was incompletely delivered into the prisoner's circulation.

7. These facts – CDCR's use of a deficient protocol, its failure to train, its evident lack of understanding of the medical issues inherent in the execution process, the failure to investigate and consider revisions in the face of apparent errors, and evidence that the thiopental was in fact not properly administered on several occasions – convince me that there is a significant, unacceptable, and easily remedied risk that inmates will be inadequately anesthetized during the execution procedure.

B. Evidence that Thiopental Was Not Successfully Administered

8. The information regarding recent executions produced by the defendants raises a number of questions about the efficacy of the CDCR's administration of thiopental.

9. The 5-gram dose of thiopental, if delivered successfully into the circulation, should completely suppress all neuronal signaling activity within the prisoner's central nervous system. Specifically, within at most a minute of delivery, the thiopental should completely ablate electrical activity in the inmate's brain. Because respiratory activity is generated and controlled by the brain, the inmate should stop breathing as soon as significant quantities of thiopental are delivered to the brain, and there should be no respiratory movement of any kind. I believe that Dr. Dershwitz would agree with these statements, as he has previously stated that the 5-gram dose of thiopental "will cause virtually all persons to stop breathing within a minute of drug administration." Dershwitz Decl. in *Cooper v. Rimmer*, ¶ 8, attached as Ex. 4 to Heath Decl. of Jan. 12, 2006. My only difference with Dr. Dershwitz in this regard, I believe, is that I would not qualify the assertion with the word "virtually," and would instead say that "successful delivery into the circulation of 5 grams of thiopental would cause the cessation of respiratory activity in all persons."

10. The execution records indicate that several inmates continued to have visible respiratory movements for several minutes after the administration of the thiopental. As I and Dr. Dershwitz have noted before, 5 grams of thiopental is a massive dose that, if successfully

administered, far exceeds the amount necessary to completely arrest respiratory activity in any prisoner. I therefore can provide no medical explanation for the inmates' continued breathing other than that the thiopental was not administered in its entirety.

11. If the full dose of thiopental was not administered successfully – as is strongly suggested by the inmates' continued breathing – those inmates faced a significant risk of remaining conscious or regaining consciousness during the lethal injection procedure. Importantly, a person who is breathing while under general anesthesia cannot be deeply anesthetized, and may well be awakened by a painful stimulation such as a surgical incision or the administration of potassium. Moreover, the repetition of this occurrence in several executions indicates that the CDCR has not taken any steps to prevent it, and indeed may not understand the medical and biological events that are taking place during the execution process.

12. The handwritten records of Stanley "Tookie" Williams's execution (Attach. 3-B to Defendants' Response to Court Ordered Discovery) indicate that Mr. Williams did not stop breathing until 12:34, upon the injection of the potassium chloride, 12 minutes after the thiopental was injected. Thus, the thiopental did not have the effect on Mr. Williams's brain and respiratory activity that would be expected with a high degree of certainty from the delivery into the circulation of the full 5-gram dose of thiopental. Absent discussion with the execution personnel I am unable to provide any explanation for the recorded events other than a failure to deliver the complete dose.

13. The execution log of Clarence Ray Allen states that Mr. Allen continued breathing for 9 minutes after the delivery of the thiopental. Again, 5 grams of thiopental, if successfully delivered into the circulation, simply should not take 9 minutes to ablate cerebral electrical activity and respiratory activity.

14. The January 29, 2002 execution log of Stephen Wayne Anderson, recently produced by the defendants, reveals that Mr. Anderson continued breathing until 12:22, 5 minutes after the thiopental was administered. Again, this persistent respiratory activity is not consistent with the expected effect of 5 grams of thiopental, which would be to stop all visible respiratory activity within a minute of its delivery into the circulation. Again, absent a satisfactory description of the events and

an explanation by the execution team personnel, I am unable to provide any explanation for the recorded events other than a failure to deliver the complete dose.

15. The March 15, 2000 execution log of Darrell Keith Rich, recently produced by the defendants, states that Mr. Rich's respirations ceased at 12:08, with the administration of the pancuronium, but that Mr. Rich had "chest movements" lasting from 12:09 to 12:10. These chest movements, beginning after Mr. Rich had ostensibly stopped breathing (and while he was still alive, as shown by his heart rate of 110 beats per minute), and 3 minutes after the administration of the thiopental, are again inconsistent with successful administration of the thiopental. The chest movements are consistent, however, with an attempt to fight against the accruing paralytic effect of the pancuronium. Had the 5-gram dose of thiopental reached Mr. Rich and had the expected effect, he would not have been able to fight against the pancuronium by attempting to breathe, nor would he even have been aware of the effect of the pancuronium. Indeed, because 5 grams of thiopental would have arrested all cerebral activity, including all respiratory drive, there would have been no effort on Mr. Rich's part to attempt to breathe during the onset of the pancuronium. Absent a satisfactory description of the events and an explanation by the execution team personnel, I am unable to provide any explanation for the recorded events other than a failure to deliver the complete dose.

16. In sum, there is evidence that of the six inmates executed by CDCR since 2000, four of them were documented by the CDCR to display activity and behavior that is inconsistent with the successful administration of 5 grams of thiopental.

C. Inaccuracies in the Execution Logs and the Need for Further Discovery

17. There are inconsistencies and alterations in the recently produced execution logs that raise questions as to who is recording the execution procedures and whether the logs provide a reliable account of the executions.

18. The notations in the handwritten account of Mr. Williams's execution contradict the execution log. As discussed above, the handwritten account indicates that Mr. Williams stopped breathing at 12:34, when the potassium was administered. The execution log, however, records that Williams's breathing stopped at 12:28, when the pancuronium was administered. It is clear from the

log that that entry has been *altered* to read "0" in the "respirations" column. This inconsistency, and the apparent alteration of the execution log, is extremely disturbing. If CDCR perceives Mr. Williams's continued respiration as problematic (and I believe that the continued respiration is extremely problematic), then is it taking the necessary and required steps to determine why this happened or ensure that it does not happen again? Further, it is an established and undisputed requirement of medical record-keeping that alterations to the record be initialed or signed by the person making the alteration, so that if in the future there is a medical or legal need to scrutinize the chart it is clear who made the alteration. Clearly there is a need for discussion with the execution personnel to find out whether they recognize that this situation is problematic and determine whether they have taken steps to remedy it.

19. The execution records of Mr. Allen are incomplete. Press accounts and Dr. St. Clair's statements show that Mr. Allen was given a second dose of potassium chloride, in a deviation from the protocol. Both the execution log and the handwritten account of the execution fail to mention the second dose. This deviation from the protocol, particularly by inadequately trained personnel, is unacceptable.

20. These inaccuracies, inconsistencies, and contradictions demonstrate the need for more information as to how the CDCR is conducting executions. Given that the documents provide a very disturbing record of previous executions, are themselves incomplete, and the protocol itself is incomplete in its failure to guide discretion and account for foreseeable errors, it is essential that injection personnel be questioned about these problematic executions prior to the conduct of any further lethal injection procedures by this team of personnel. Moreover, it is essential that CDCR be asked about the medical review and investigation it conducts. Notably, other states' corrections departments have permitted members of their execution teams to explain and describe the conduct of prior executions. As discussed above, the documents now available raise a number of questions regarding the adequacy of the delivery of the drugs, particularly the thiopental. Talking to the personnel responsible for the delivery of the drugs represents an essential step towards resolving these questions.

D. The Use of Pancuronium

21. During the proceedings before the Court on January 26, 2006, counsel for defendants stated: "[I]f you injected somebody who was conscious with the [pancuronium], while it would certainly render them unconscious in a fairly short amount of time, they would stop breathing, it would for at least some period of consciousness be a very painful result because they would be suffocating. *There would be some indication of that. People would know that was happening.*" Transcript of Proceedings, Jan. 26, 2006, at 42 (emphasis added). This statement is inaccurate.

22. An inmate given pancuronium would not suffocate until the pancuronium paralyzes his muscles. The painful suffocating to which counsel refers would in fact probably not begin until the inmate's other voluntary muscles are paralyzed, because generally the diaphragm and other respiratory muscles are among the last to be affected by pancuronium. An inmate who was conscious and aware of suffocation after the administration of the pancuronium therefore would not be able to communicate his suffering in any way that would be perceptible to the witnesses and the execution team. The statement that eyewitnesses would be able to detect an inmate's suffering if he were conscious but paralyzed is thus completely inaccurate.

23. A trained anesthesiologist or veterinarian observing an inmate immobilized by pancuronium from close range would, given the appropriate equipment and access, be able to detect the subtle clues that the inmate was in fact conscious and suffering. A person who is in great pain or is terrified might have dilated pupils, might begin sweating, or might lacrimate (secrete tear fluid into the eyes). Increased heart rate and blood pressure also can be signs that an inmate is not adequately anesthetized. These signs could be assessed and interpreted only by a person who is trained and experienced in assessing anesthetic depth, and who is situated immediately adjacent to the prisoner (i.e., close enough to open their eyes to inspect the pupils and to touch or closely scrutinize the skin of the forehead to see if it is moist with sweat). Given that no member of the execution team is present in the room with the inmate after the drugs are administered, the CDCR has guaranteed that no member of the team will be able to detect these subtle yet critical signs of inadequate anesthetic depth. Moreover, even if one of the injection team members were in the chamber observing the

inmate, such observation would be useless if the staff member had no training in the assessment of anesthetic depth.

E. The EKGs Recently Produced By Defendants

24. On Saturday, February 4, 2006, I received copies of the EKG recordings from recent executions. Reviewing and analyzing the EKGs is a project that will take several days, and I can not start the review until the present declaration is completed. Of note, the review process will be slowed by the lack of "time stamp" data on the EKG strips. At this point it would be premature to make conclusive statements about the significance and implications of the EKG data.

F. The *Lancet* Article and Toxicology Data

25. It is my opinion that the article entitled *Inadequate Anaesthesia in Lethal Injection for Execution*, published in *The Lancet* in 2005, is flawed. Its conclusion that 43% of inmates whose postmortem blood toxicology was measured may have been conscious, is not accurate. The study's conclusions were drawn entirely on the basis of toxicology data obtained more than several hours after death. As the post-mortem interval (the time between death and the sampling of blood) increases, thiopental is passively redistributed throughout the body, a phenomenon that results in differing levels of thiopental in different places within the body. Toxicology data obtained more than several hours after death therefore should not be used to argue that the concentration was low (or the anesthesia was inadequate) at the time of the execution.

26. After reviewing over 200 toxicology reports from lethal injection procedures across the country, I concluded that toxicology data must be obtained within a couple hours of death in order to provide reliable indicators of an inmate's risk of consciousness during the lethal injection procedure. That belief formed the basis of the letter that I and other experts wrote to *The Lancet* taking issue with the study's methods for concluding that 43% of examined inmates may have been conscious.

27. I continue to believe, however, that toxicology data obtained within the first hours after death can provide insight into an inmate's thiopental levels during the execution. I have reviewed toxicology data from 12 states (Arizona, Connecticut, Delaware, Florida, Georgia,

Kentucky, Maryland, North Carolina, Oklahoma, Oregon, South Carolina, and Virginia). Of those reports, a subset contain data obtained shortly after death. I know of no reason to conclude that these data are unreliable. Of these data, a number show low thiopental concentrations that are not consistent with a surgical plane of anesthesia. Because a person who is rendered unconscious but not placed in a surgical plane of anesthesia can wake up when subjected to extremely painful stimuli, the low thiopental levels are extremely troubling.

28. Should the Court desire a more full explanation regarding post-mortem thiopental toxicology I am ready and willing to testify in great detail about this subject.

G. The Differences Between the Missouri's Femoral Line Procedure and the *Nelson* Cutdown

29. Counsel for Mr. Morales has asked me to explain the difference between Missouri's procedure for placing a femoral central line, at issue in *Taylor v. Crawford*, and the cutdown procedure that was the subject of *Nelson v. Campbell*. Although the two procedures have the same goal – reaching a central vein in order to deliver the lethal injection drugs into it – Missouri's procedure is far less invasive than Alabama's cutdown, and is performed by a trained and experienced licensed surgeon.

30. Missouri delivers the lethal injection drugs to every inmate through a central (deep) vein. This requires that the execution team perform a percutaneous central line placement to insert a catheter in a central vein, generally, the femoral vein in the inmate's groin. Missouri's procedure requires that the surgeon insert a syringe with a hollow needle into the inmate's groin. Once he has penetrated the vein, he removes the syringe, leaving the needle in the vein. He then threads a wire through the hollow needle into the vein and removes the needle, leaving the wire. Finally, the surgeon inserts a catheter into the vein by threading it along the wire into the vein, and removes the wire. Typically the central line is then sutured to the underlying region, in this case the groin.

31. The cutdown procedure at issue in *Nelson v. Campbell* provided that a member of the execution team – whose training, credentials, proficiency, accreditation, and licensure were unknown – would make an incision into the inmate's tissue, cauterizing the surgically exposed flesh to stop bleeding. A steel retractor would be placed to stretch the incision open, and a scalpel and/or scissors

would be used to dissect and cut down to the level within the body that would expose a segment of the vein. The catheter would be inserted into the vein through this incision. I stated at the time, and continue to believe, that Alabama's cutdown procedure was dangerous and unnecessary, and that a percutaneous line placement would be a safer and less invasive means of inserting a catheter into a central vein.

I declare under penalty of perjury under the laws of the state of California and the United States of America that the foregoing is true and correct. Executed this 6th day of February, 2006 in New York City, New York.

By: _____

Dr. Mark Heath

employees under your charge carried out the executive protocol here as directed.

THE WITNESS: Yes.

THE COURT: Okay.

MR. LEE: Was that an answer?

THE COURT: It was. The answer is yes.

Q Okay. So during the execution different things take place in different places, correct?

A Correct.

Q Syringes are --

MR. VORHIS: Judge, --

THE COURT: Objection sustained. You're going so far afield now, Mr. Lee. You and I have had this conversation so many times. The issue here is whether or not these chemicals in combination create such excruciating foreseeable suffering that they constitute cruel and unusual punishment. That is the issue.

We're not going into -- you have been trying so hard to challenge lethal injection generally. The Fourth Circuit said you can't do it. You cannot do it. This is not a 2254, it is a 1983.

MR. LEE: Yes, Your Honor.

THE COURT: I don't need to remind you. You know that. But please keep both feet inbounds, please.

MR. LEE: Yes, Your Honor. I was just about to

ask at one point in the execution the drugs are prepared by the Department of Corrections team members.

THE COURT: All right. You may ask that.

Q Is that correct?

A That's correct.

Q And those are prepared where?

A In the L Unit.

Q And is that something that in your responsibilities for oversight you would observe happening?

A No.

Q Now, during an execution there's a gurney in a room that witnesses can see, is that correct?

A That is.

Q The inmate is on that gurney?

A That is correct.

Q The IV is placed in the inmate while lying on that gurney, is that correct?

A That's correct.

Q And do you observe your team members actually placing the IV in each execution for which you're responsible?

MR. VORHIS: Objection.

THE COURT: Overruled. Go ahead.

A I do observe it. I'm not medically trained. I'm

not the one that trains them to do IVs. I'm not -- I don't know pharmacy. I don't supervise the mixing of the drugs.

Q So you don't supervise the mixing of the drugs, and you're also not trained to place the IV?

A That's correct.

Q But you're responsible for that oversight?

A I'm responsible to see if things happen in a certain sequence.

Q Now, there is a curtain behind the inmate and behind there is actually where the syringes are, is that correct?

A That's correct.

Q And certain members of the execution team are placing the syringes and the needle into tubing in -- back behind that curtain. Now, do you observe that as well as what's happening in the room on the other side of the curtain?

A I'm aware --

THE COURT: Mr. Lee, explain to me how that deals with the chemical reaction here.

MR. LEE: Your Honor, because the mixing of the chemicals and the delivery of the chemicals both and any -- anything -- any problems in delivering the chemicals can occur at each of those three places, and

I don't think -- I think the Warden is saying he's not actually in all the places.

THE COURT: Right. But the objection to that on grounds of relevance is sustained because, again, you're getting into the risk of an error or accident happening in the administration, and that is not relevant to the issue of the interaction of these chemicals. Objection is sustained.

Go ahead. Move on.

Q Do you have responsibility with oversight here as part of your responsibilities to amend procedure on a case by case basis if a need arises to amend those procedures?

A No.

MR. LEE: Your Honor, in our -- in our hearing the other day, it was very clear we were asking -- we were discussing the part of the protocol, and this was the witness -- he asked for a witness who could respond to that proviso. The Court pointed out --

THE COURT: What proviso is that, Mr. Lee, so I understand you?

MR. LEE: In DOP 426.

THE COURT: Okay.

MR. LEE: On Page 5 at the bottom just below Part II, Listing of Procedure, and of the procedures

described in the division operating procedure may be amended as needed on a case by case basis when circumstances require special procedures to carry out the sentence of death.

And our point was that that gave -- it seems like absolute discretion to amend whatever is in this protocol, and we wanted -- we asked in our interrogatory who could do that. We were told that the Director has the final authority, and because of that we attempted to have the Director appear today.

THE COURT: And I assume your only issue is whether or not there will be any changes in this particular case with respect to your client?

MR. LEE: Or in other -- in other cases.

THE COURT: You're not -- you can't make a general challenge to the lethal injection. I know that's what you're trying to do.

MR. LEE: Judge -- I'm sorry, go ahead.

THE COURT: The question is applied to your client. I think a 1983 is plaintiff specific, is it not?

MR. LEE: It is Your Honor.

THE COURT: Okay. All right. So the question is whether or not in the case with respect to your client there will be any changes in the protocol, is that

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Attorneys For Plaintiff MICHAEL ANGELO MORALES

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

MICHAEL ANGELO MORALES, Plaintiff, v. RODERICK Q. HICKMAN, Secretary of the California Department of Corrections and Rehabilitation; STEVEN ORNOSKI, Warden, San Quentin State Prison, San Quentin, CA; and DOES 1-50, Defendants.	Case No. C 06-0219 (JF) **AMENDED COMPLAINT FOR EQUITABLE AND INJUNCTIVE RELIEF [42 U.S.C. § 1983]** **EXECUTION IMMINENT: EXPEDITED REVIEW REQUESTED**

E.R. 0256

NATURE OF ACTION

1. This action is brought pursuant to 42 U.S.C. § 1983 for violations and threatened violations of the right of plaintiff to be free from cruel and unusual punishment under the Eighth and Fourteenth Amendments of the United States Constitution. Plaintiff seeks temporary, preliminary, and permanent injunctive relief to prevent the defendants from executing plaintiff by means of lethal injection, as that method of execution is currently used in California. Plaintiff contends that lethal injection, as performed in California, unnecessarily risks infliction of pain and suffering. Plaintiff further contends that the use of pancuronium bromide, a paralytic agent that acts as a chemical veil over the lethal injection process, disguises the pain and suffering to which he will be subjected. Plaintiff additionally contends that defendants, as a result of their failure to use medically approved procedures and properly trained personnel, have inflicted pain and torture on several executed prisoners in the past, making plaintiff certain he will suffer the same fate unless defendants adopt a humane and safe execution protocol.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (federal question), § 1343 (civil rights violations), § 2201 (declaratory relief), and § 2202 (further relief). This action arises under the Eighth and Fourteenth Amendments to the United States Constitution and under 42 U.S.C. § 1983.

3. Venue is proper pursuant to 28 U.S.C. § 1391(b) in that plaintiff is currently incarcerated at San Quentin State Prison ("San Quentin") in San Quentin, California, located in this District. All executions conducted by the State of California ("State") occur at San Quentin. The events giving rise to this complaint have occurred and will occur in this District.

THE PARTIES

4. Plaintiff Michael Angelo Morales is a United States citizen and a resident of the State. He is currently a death-sentenced prisoner under the supervision of the California Department of Corrections. He is held at San Quentin State Prison, San Quentin, California, 94974.

5. Defendant Roderick Q. Hickman is the Secretary of the California Department of Corrections.

6. Defendant Steven Ornoski is the Warden of San Quentin State Prison, where the plaintiff is incarcerated and where the plaintiff's execution is scheduled to occur.

7. Plaintiff is ignorant of the true names of Does 1-50 but alleges that they have or will participate in plaintiff's execution by virtue of their roles in designing, implementing, and/or carrying out the lethal injection process. When plaintiff discovers the Doe Defendants' true identities, he will amend his complaint accordingly.

GENERAL ALLEGATIONS

8. On January 18, 2006, a public session was held in the Superior Court of Ventura County in the case of People v. Morales, No. CR 17960, at which hearing the court set February 21, 2006 as the date of execution of Mr. Morales' judgment of death.

9. Under California law, death sentences shall be carried out by "administration of a lethal gas or by an intravenous injection of a substance or substances in a lethal quantity sufficient to cause death, by standards established under the direction of the Department of Corrections." Cal. Penal Code § 3604(a). The statute prescribes no specific drugs, dosages, drug combinations, or the manner of intravenous line access to be used in the execution process; nor does the statute prescribe any certification, training, or licensure required of those who participate in the execution process. All of the details of the execution process are to be determined by the Department of Corrections.

10. The Department of Corrections has decided to execute plaintiff by poisoning him with a lethal combination of three chemical substances: sodium pentothal, a short-acting barbiturate; pancuronium bromide, which paralyzes all voluntary muscles; and potassium chloride, an extremely painful chemical which activates the nerve fibers lining the prisoner's veins and interferes with the heart's contractions, causing cardiac arrest.

11. In performing plaintiff's execution by lethal injection, the Department of Corrections will follow the protocol established in San Quentin Operational Procedure No. 770. The protocol by which lethal injection executions are performed under Procedure No. 770 violates constitutional and statutory provisions enacted to prevent cruelty, pain, and torture.

12. Procedure No. 770 was adopted without any medical research or review to determine that a prisoner would not suffer a painful death. No member of the medical community was involved in its adoption. The procedure was adopted by the former Warden of San Quentin, Daniel Vasquez, after observing two executions in Texas, without any input from or consultation with medical personnel.

13. The absence of standardized procedures for administration of the chemicals, the lack of qualifications of the personnel involved in the process, and the combination of the three particular chemicals used in Procedure No. 770 create a grave and substantial risk that plaintiff will be conscious throughout the execution process and, as a result, will experience an excruciatingly painful and protracted death.

14. Procedure No. 770 lacks medically necessary safeguards, thus increasing the risk that plaintiff will suffer unnecessary pain during the lethal injection process. There is no standardized time to administer each of the three chemicals. The protocol identifies no procedures for ensuring that the anesthetic agent is properly flowing into the prisoner, and it identifies no procedures for ensuring that the prisoner is properly sedated prior to the administration of the lethal chemicals as would be required in any medical or veterinary procedure before the administration of a neuromuscular blocking agent, such as pancuronium bromide, or the administration of a painful potassium chloride overdose.

15. The protocol established in Procedure No. 770 does not establish any minimum qualifications or expertise required of the personnel who perform all of the tasks in the lethal injection process. There are no guidelines upon which these personnel can rely if they are required to exercise their discretion during the process. The protocol has no plan in place if the plaintiff requires medical assistance during the execution.

16. Sodium pentothal, in an ordinary clinical dose, is a very short-acting barbiturate that is usually administered only during the preliminary phase of anesthesia administration. There is a reasonable likelihood that sodium pentothal, if ineffectively delivered (which is particularly likely given the inadequacy of the administration procedures under Procedure No. 770), will not provide a sedative effect for the duration of the execution process. Without adequate sedation, plaintiff will

experience excruciating pain as a result of the conscious asphyxiation caused by pancuronium bromide and the painful internal burn and cardiac arrest caused by a potassium chloride overdose.

17. Pancuronium bromide, the second chemical administered in the lethal injection process, paralyzes voluntary muscles, including the diaphragm, but it does not affect consciousness or the perception of pain. Pancuronium bromide, administered by itself as a "lethal dose," would not result in a quick death; instead, it would ultimately cause someone to suffocate to death while still conscious. There is no indication in the Department of Correction's lethal injection protocol, however, that pancuronium bromide is used to cause death. It therefore is completely unnecessary in the lethal injection process and only serves to mask any pain or suffering that the plaintiff may experience.

18. Pancuronium bromide could not lawfully be used alone as the fatal agent because causing death by suffocation violates the Eighth Amendment's prohibition against cruel and unusual punishment.

COUNT I

VIOLATION OF RIGHT TO BE FREE FROM CRUEL AND UNUSUAL PUNISHMENT PURSUANT TO THE EIGHTH AND FOURTEENTH AMENDMENTS TO THE UNITED STATES CONSTITUTION (42 U.S.C. § 1983)

19. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 18.

20. Defendants Roderick Q. Hickman, Steven Ornoski, and Doe Defendants are acting under color of California law in causing to be administered to plaintiff chemicals that will cause unnecessary pain in the execution of a sentence of death, thereby depriving plaintiff of his rights under the Eighth and Fourteenth Amendments to be free from cruel and unusual punishment, in violation of 42 U.S.C. § 1983.

21. The California Department of Corrections Procedure No. 770, which specifies the State's lethal injection protocol, violates plaintiff's rights under the cruel and unusual punishment clause of the Eighth Amendment because (a) the protocol creates the unreasonable and unacceptable risk of